



Lawsuit. The UFCW Suit and the Iron Workers Lawsuit are hereinafter collectively referred to as the “Pennsylvania Lawsuits”); and

- c. *State of Arkansas, et al. v. Purdue Pharma, L.P., et al.*, Case No. CV-2018-268, filed in the Circuit Court of Crittenden County, Arkansas (the “Arkansas Lawsuit”);

2. Pernix requested that Navigators defend and indemnify it in the Opioid Lawsuits under a Products-Completed Operations Liability policy (the “Products Policy”), a Commercial General Liability Policy (the “CGL Policy”), and a Commercial Umbrella Liability Policy (the “Umbrella Policy”) (collectively, the “Policies”), all in effect from November 30, 2017 to November 30, 2018.

3. Navigators disputes any obligation to defend or indemnify Pernix for any of the Opioid Lawsuits and seeks a declaration that it has no duty to defend or indemnify Pernix for any of the Opioid Lawsuits.

4. In the alternative, Navigators seeks an allocation between covered and uncovered costs associated with the defense and indemnity of the Opioid Lawsuits.

### **PARTIES**

5. Navigators is an insurance company organized under the laws of the State of New York, with its principal place of business located in New York, New York.

6. Pernix is a pharmaceutical company that manufactures, develops and markets prescription pharmaceuticals, including Zohydro ER, an opioid.

7. Pernix is organized under the laws of the State of Maryland, with its principal place of business located in Morristown, New Jersey.

8. Pernix obtained the Policies from Navigators through a broker located in Philadelphia, Pennsylvania.

### **JURISDICTION AND VENUE**

9. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the matter in controversy arises between citizens of different states, and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

10. Declaratory relief is authorized pursuant to 28 U.S.C. § 2201.

11. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claim occurred in this District.

### **FACTUAL ALLEGATIONS**

#### **The Pennsylvania Lawsuits**

12. The Complaint in the UFCW Suit was filed on April 24, 2018 by the UFCW, Local 23 and Employers Health Fund against Pernix and various other pharmaceutical manufacturers. A copy of the Complaint is attached hereto as Exhibit “A.”

13. The Complaint in the Iron Workers Suit was filed on May 23, 2018 by the Iron Workers’ District Council of Philadelphia and Vicinity Benefit Fund against Pernix and various other pharmaceutical manufacturers. A copy of the Complaint is attached hereto as Exhibit “B.”

14. The allegations of the Pennsylvania Lawsuits are nearly identical. Both allege that Pernix and the other defendants “engaged in an intentional, decades-long pattern of deceptive and misrepresentative conduct” regarding the risks of using opioids, leading to a vast increase in overdose-related deaths in the Commonwealth of Pennsylvania and in Philadelphia.

15. Each of the Pennsylvania Lawsuits alleges the following four causes of action against Pernix:

- a. Count One: Civil insurance fraud. Specifically, Pernix and the other defendants are alleged to have knowingly and intentionally defrauded the plaintiffs, who are considered insurers, through the misrepresentation of the dangers and benefits of opioids.
- b. Count Two: Disgorgement of profits. Specifically, Pernix and the other defendants are alleged to have been unjustly enriched through their deceptive and wrongful conduct related to the sale of opioids.
- c. Count Three: Breach of implied warranties. Specifically, Pernix and the other defendants are alleged to have impliedly warranted that opioids were appropriate for long-term use even though they knew or should have known that opioids were ineffective and dangerous when used in the long term.
- d. Count Four: Civil conspiracy. Specifically, Pernix and the other defendants are alleged to have conspired amongst themselves to commit unlawful acts, including the insurance fraud alleged in Count One, and to present false or misleading information about opioids in order to drive sales.

16. The plaintiffs in the Pennsylvania Lawsuits seek damages for Pernix's intentional conduct, restitution, disgorgement and statutory penalties.

#### **The Arkansas Lawsuit**

17. The Second Amended Complaint in the Arkansas Lawsuit was filed on April 2, 2018 by the State of Arkansas and its county and city political subdivisions against Pernix and various other pharmaceutical manufacturers and distributors and health care providers. A copy of the Second Amended Complaint is attached hereto as Exhibit "C."



18. The Arkansas Lawsuit alleges that Pernix and other defendants engaged in a marketing scheme to increase opioid sales by, among other things, downplaying the risk of opioid addiction, promoting the concept of “pseudoaddiction,” exaggerating the effectiveness of addiction prevention and screening tools, claiming that opioid dependence and withdrawal are easily managed, denying the risks of increasing opioid dosages, and falsely touting the benefits of long-term opioid use. The alleged actions purportedly resulted in a dramatic increase in demand for public services and in associated costs to Arkansas and its political subdivisions.

19. The Arkansas Lawsuit asserts nine causes of action against Pernix:

- a. Count One: Negligence/gross negligence. Specifically, Pernix and the other defendants are alleged to have breached their duty of reasonable care in the “manufacture, distribution, dispensing, and prescribing of opioids” and their duty “not to endanger public health, welfare, or safety.”
- b. Count Two: Common law public nuisance. Specifically, Pernix and the other defendants are alleged to have created or participated in the creation of a nuisance in the form of the over-saturation of opioids and widespread use of opioids for non-medical purposes.
- c. Counts Three: Violations of the Arkansas Uniform Narcotic Drug Act, Ark. Code Ann. §§ 20-64-201 *et seq.* Specifically, Pernix and the other defendants are alleged to have, *inter alia*, disregarded statutory and regulatory rules regarding safe distribution and dispensing methods and consciously oversupplied the Arkansas market with opioids.
- d. Count Four: Accomplice to violations of the Arkansas Uniform Narcotic Drug Act, Ark. Code Ann. §§ 5-2-403; 20-64-201 *et seq.* Specifically, Pernix and

the other defendants are alleged to have actively aided in, agreed to aid in, and failed to prevent one another from violating the Arkansas Uniform Narcotic Drug Act as set forth in Count Three.

- e. Count Five: Civil conspiracy to violate the Arkansas Uniform Narcotic Drug Act. Specifically, Pernix and the other defendants are alleged to have agreed to oversupply prescription opioids in disregard of the Arkansas Uniform Narcotic Drug Act.
- f. Count Six: Violations of the Arkansas Uniform Controlled Substances Act, Ark. Code Ann. §§ 5-64-101 *et seq.* Specifically, Pernix and the other defendants are alleged to have possessed, delivered, manufactured, and trafficked controlled substances in knowing violation of their statutory and regulatory duties to maintain effective controls against opioid diversion.
- g. Count Seven: Accomplice to violations of the Arkansas Uniform Controlled Substance Act. Specifically, Pernix and the other defendants are alleged to have actively aided in, agreed to aid in, and failed to prevent one another from violating the Arkansas Uniform Controlled Substances Act as set forth in Count Six.
- h. Count Eight: Civil conspiracy to violate the Arkansas Uniform Controlled Substances Act. Specifically, Pernix and the other defendants are alleged to have agreed to oversupply prescription opioids in disregard of the Arkansas Uniform Controlled Substances Act.
- i. Count Nine: Violations of the Arkansas Drug Dealer Liability Act, Ark. Code Ann. §§ 16-124-101 *et seq.* Specifically, Pernix and the other defendants are

alleged to have knowingly participated in the illegal drug market in violation of the Arkansas Drug Dealer Liability Act.

20. The plaintiffs in the Arkansas Lawsuits seek damages for Pernix's intentional conduct, restitution, disgorgement, statutory penalties and multiplied damages.

**The Products Policy**

21. Navigators issued GLS Elite Products-Completed Operations Liability Coverage, policy number PH17LGL0A78IVNV, to Pernix for the period from November 30, 2017 to November 30, 2018. A true copy is attached as Exhibit "D."

22. The Products Policy's **Insuring Agreements** provides:

The Company will pay amounts in excess of the deductible or retention up to the limit of liability for **damages** that an **Insured** becomes legally liable to pay as a result of a **products-completed operations hazard claim**.

23. The **Insuring Agreements** section further provides:

The Company has the right and duty to defend any covered **claim**, against an **Insured**, seeking **damages** that are payable under the terms of this Products Policy, even if any of the allegations of such **claim** are groundless, false or fraudulent. . . .

24. The Products Policy defines **damages** as:

judgments; awards; and settlements, but only if made with the Company's prior written consent. **Damages** do not include:

- A. restitution and disgorgement of profits, fees, costs and expenses paid or incurred by an **Insured**, no matter whether claimed as restitution of specific funds, forfeiture, financial loss, set-off or otherwise; nor economic injuries that are a consequence of any of the foregoing;
- B. civil or criminal fines, sanctions, penalties or forfeitures, whether pursuant to law, statute, regulation or court rule;

- C. the multiplied portion of multiplied awards imposed pursuant to any statute or regulation requiring such awards;
- D. injunctive or declaratory relief;
- E. any amount that is not insurable under any applicable statute or regulation;
- F. any amounts for which an **Insured** is liable due to an act or omission in knowing violation of any written contract or agreement; or
- G. plaintiff's attorney fees associated with any of the above.

25. The Products Policy defines **products-completed operations hazard claim** as “a **claim** alleging a **products-completed operations hazard** and arising out of an **occurrence**.”

26. The Products Policy defines **products-completed operations hazard** as:

- A. **bodily injury** or **property damage** arising out of **your product** or **your work**; or
- B. **personal or advertising injury** but solely to the extent such **personal or advertising injury** arises out of **clinical trials** sponsored by **you** and solely to the extent a **clinical trial** participant incurs such **personal or advertising injury**.

27. The Products Policy defines **bodily injury**, in relevant part, as “physical harm, sickness or disease sustained by a person including resulting mental injury, mental anguish, shock or death.”

28. The Products Policy defines **occurrence** as “an accident, including continuous or repeated exposure to the same general harmful conditions.”

29. The Products Policy contains several potentially applicable exclusions.

30. Exclusion **C. Banned Materials** provides that there is no coverage under the Products Policy:

based on or arising out of **your product** or **your work** that is manufactured, developed, designed, created, tested, sold, leased,

licensed, rented, handled, marketed, distributed or disposed of by **you** or others on **your** behalf in known violation of any law, statute, ordinance or regulation. For purposes of determining the applicability of this exclusion:

31. Exclusion **D. Breach of Contract**, in relevant part, excludes coverage for “any **claim** or suit based on or arising directly out of . . . breach of express or implied warranty.”

32. Exclusion **F. Criminal, Dishonest, Fraudulent, Malicious Conduct or Acts of Intentional Wrongdoing** provides that there is no coverage under the Products Policy:

based on or arising out of criminal, dishonest, fraudulent or malicious conduct or acts of intentional wrongdoing by the **Insured**; provided, however, that the Company shall provide the **Insured** with a defense of such **claim** unless or until the dishonest, fraudulent, malicious or act of intentional wrongdoing has been determined by a trial verdict, court ruling, regulatory ruling or legal admission, but such a defense will only be provided in a civil action or regulatory proceeding for **claims** asserted by a **bodily injury** or **property damage** claimant in his or her individual capacity. The defense of a **claim** will not waive the rights of the Company to deny indemnity under the applicable Products Policy.

33. Exclusion **H. Expected or Intended Injury** provides that there is no coverage under the Products Policy:

based on or arising out of any actual or alleged **bodily injury** or **property damage** expected or intended from the standpoint of the **Insured**. This exclusion does not apply to:

1. **bodily injury** resulting from the use of reasonable force to protect persons or property; or
2. **bodily injury** that is intended or can be expected to result from the reasonable use of **your product**.

34. Exclusion **M. Medical Services** provides that there is no coverage under the Products Policy:

based on or arising out of **medical services**. However this exclusion does not apply to:

1. physicians, dentists, nurses, emergency medical technicians or paramedics employed by **you** to the extent that they are rendering first aid; or
2. to any **products-completed operations hazard claim** made against a **clinical trial investigator**.

35. The Products Policy defines **medical services** as:

- A. dental, medical, mental health, nursing, surgical, imaging, clinical testing or other similar service providing direct care to a patient and performed by a medical intern, resident, technician, nurse, physician or other medical professional;
- B. the furnishing of food, beverages, medications or appliances in connection with such services; or
- C. the postmortem handling of human bodies.

#### **The CGL Policy**

36. Navigators issued Commercial General Liability Coverage, policy number CH17NCP020480-00, to Pernix for the period from November 30, 2017 to November 30, 2018.

A true copy is attached as Exhibit “E.”

37. The CGL Policy’s **Insuring Agreement** section provides, in relevant part:

We will pay those sums that the insured becomes legally obligated to pay as damages because of “bodily injury” or “property damage” to which this insurance applies. We will have the right and duty to defend the insured against any “suit” seeking those damages. However, we will have no duty to defend the insured against any “suit” seeking damages for “bodily injury” or “property damage” to which this insurance does not apply. . . .

38. The CGL Policy defines “bodily injury” as “bodily injury, sickness or disease sustained by a person, including death resulting from any of these at any time.”

39. The CGL Policy defines “occurrence” as “an accident, including continuous or repeated exposure to substantially the same general harmful conditions.”

40. Exclusion **r. Products-Completed Operations Hazard** provides:

This insurance does not apply to any injury, damage, loss, cost or expense, including but not limited to “bodily injury” or “property damage” arising out of, included within or in any way related to the “products-completed operations hazard”.

41. The CGL Policy provides that a “products-completed operations hazard”:

includes any injury or damage arising out of or in any way related to:

- a. “Your product” or “your work” whether or not:
  - i. Such products or work are on or away from your premises;
  - ii. Possession of such products or work has been relinquished;
  - iii. The product or work is completed or still in progress, or in any stage of trial, design, evaluation, demonstration or testing;
  - iv. Tools, uninstalled equipment or abandoned or unused materials are present on or away from your premises; or
  - v. Products or operations for which the classification, listed in the Declarations or in a policy schedule, states that product-completed operations are subject to the General Aggregate Limit;
- b. Any trial, design, evaluation, demonstration or testing whether provided by physicians or others including, but not limited to, “clinical trial(s)” of “your product” or “your work” including, but not limited to the evaluation or testing of drugs, cosmetics, chemical or biological agents, pharmaceuticals, medical devices, surgical devices or dental devices on human, animal or other subjects for any purpose whatsoever;
- c. An error, omission, defect or deficiency in:
  - i. Any test performed; or
  - ii. Any evaluation or consultation or advice given by or on behalf of any insured;
- d. The reporting of or reliance upon any test performed or any evaluation, consultation or advice given by or on behalf of any insured;

- e. An error, omission, defect or deficiency in experimental data or the interpretation of data; or
  - f. Violation of any intellectual property rights, including but not limited to patent, copyright, trademark or service mark, trade name, trade secret or other designation of origin or authenticity in any way related to “your product” or “your work”, or the work or product of others.
42. The CGL Policy provides that “your product”:
- a. Means:
    - i. Any goods or products, other than real property, designed, tested, studied, evaluated, manufactured, sold, handled, distributed, licensed or disposed of by:
      - 1. You, whether on your own behalf or on behalf of any others
      - 2. Others trading under your name; or
      - 3. A person or organization whose business or assets you have acquired; or
    - ii. Containers (other than vehicles), materials, parts of equipment furnished in connection with, or in any way related to, any of the foregoing in (1) above.
  - b. Includes:
    - i. Warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of “your product”;
    - ii. Consultations or advice given at any time with respect to the design, fitness, quality, durability, performance or use of “your product”;
    - iii. The providing or failure to provide warnings or instructions; and
    - iv. Vending machines or other property located for the use of others whether or not sold.

43. The CGL Policy provides that “your work”:

- a. Means:



- i. Work or operations, included but not limited to design, testing, “clinical trial(s)”, demonstrations, studies or evaluations performed by you or on your behalf;
  - ii. Materials, parts or equipment furnished in connection with such work or operations.
- b. Includes:
- i. Warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of “your work”;
  - ii. Consultations or advice given at any time with respect to the design, fitness, quality, durability, performance or use of “your work”; and
  - iii. The providing of or failure to provide warnings or instructions.

44. Exclusion **s. Health Care and “Life Science Fields of Science” Services** provides in relevant part:

- 1. This insurance does not apply to any injury, damage, loss, cost or expense, including but not limited to “bodily injury”, “property damage” or “personal and advertising injury” arising out of or in any way related to:
    - a. Medical, surgical, dental, x-ray or nursing service, treatment, products, advice or instruction;
    - b. Any health or therapeutic service, treatment, product, advice or instruction;
- \* \* \*
- d. The furnishing or dispensing of drugs or medical, dental or surgical supplies, products or appliances;

\* \* \*

**The Umbrella Policy**

45. Navigators issued Commercial Umbrella Liability Coverage, policy number CH17UMF922034IV, to Pernix to for the period from November 30, 2017 to November 30, 2018.

A true copy is attached as Exhibit “F.”

46. The Umbrella Policy's Insuring Agreement provides, in relevant part:

A. Coverage A – Excess Liability

1. We will pay on behalf of the insured and in excess of “underlying limits” those sums the insured becomes legally obligated to pay as damages for “loss” to which this insurance applies. This insurance applies only if:
  - a. the “loss” is caused by an “event” that takes place in the “coverage territory;”
  - b. the “loss” occurs during the “policy period;” and
  - c. the “scheduled underlying insurance” applies to the “loss.”

\* \* \*

B. Coverage B – Umbrella Liability

1. When Coverage A – Excess Liability does not apply, we will pay on your behalf and in excess of the “retained limit,” those sums you become legally obligated to pay as damages because of “bodily injury” or “property damage” to which this insurance applies. This insurance applies only if the “bodily injury” or “property damage:”
  - a. is caused by an “occurrence” in the “coverage territory;” and
  - b. occurs during the “policy period,” whether or not such “bodily injury” or “property damage” continues, progresses, changes or resumes after the “policy period.”

\* \* \*

47. The Exclusions section of the Umbrella Policy provides, in relevant part:

The EXCLUSIONS sections of the “scheduled underlying insurance” are made part of this policy and apply to Coverage A – Excess Liability and Coverage B – Umbrella Liability. If an inconsistency or contradiction exists between an Exclusion of this policy and an Exclusion of the “scheduled underlying insurance” the Exclusion of this policy will apply.

48. The Umbrella Policy incorporates by reference the definitions sections of the “scheduled underlying insurance.”

49. The Umbrella Policy defines “scheduled underlying insurance” as:

the insurance policy, listed in the Schedule of Underlying Insurance in the Declarations, or its renewal or replacement, which applies to the “loss,” or would applied but for:

- a. an exclusion in the “scheduled underlying insurance;”
- b. the exhaustion or erosion of an aggregate limit of insurance; or
- c. any failure to maintain “scheduled underlying insurance” in accordance with SECTION IV – CONDITIONS, 8. Maintenance of Scheduled Underlying Insurance.

If more than one policy is listed in the Schedule, the “scheduled underlying insurance” is the policy which applies to the “loss” or would have applied to the “loss” but for the reasons a., b., c., listed above.

50. The Umbrella Policy lists the CGL Policy, but not the Products Policy, in the Schedule of Underlying Insurance.

#### **Coverage Dispute**

51. Pernix has requested that Navigators defend and indemnify it in the Opioid Lawsuits.

52. By letter dated October 23, 2018, Navigators disclaimed any duty to defend or indemnify Pernix in the Pennsylvania Lawsuits under the Policies.

53. By letter dated October 23, 2018, Navigators disclaimed any duty to defend Pernix in the Arkansas Lawsuit under the CGL and Umbrella Policies; disclaimed any duty to defend or indemnify Pernix on Counts Three to Nine of the Arkansas Lawsuit under the Products Policy; and

reserved the right to disclaim any duty to defend or indemnify Pernix on Counts One and Two of the Arkansas Lawsuit under the Products Policy.

54. Pernix disputes the propriety of Navigator's disclaimers.

**COUNT I – NO DUTY TO DEFEND**  
**(Products Policy)**

55. Navigators incorporates by reference the allegations in Paragraphs 1 through 54 above as if fully set forth herein.

56. The Opioid Lawsuits do not seek "damages" for "bodily injury" caused by an "occurrence" as these terms are defined within the Products Policy.

57. Instead, the Opioid Lawsuits seek economic losses, restitution, statutory penalties, multiplied damages and equitable relief based upon Pernix's intentional conduct.

58. Additionally, recovery for some or all of the damages sought in the Opioid Lawsuits is precluded by the following exclusions:

- a. Exclusion C, which provides that the Products Policy does not apply to claims based on or arising out of banned materials;
- b. Exclusion D, which provides that the Products Policy does not apply to claims based on a breach of warranty;
- c. Exclusion F, which provides that the Products Policy does not apply to claims "based on or arising out of criminal, dishonest, fraudulent or malicious conduct or acts of intentional wrongdoing";
- d. Exclusion H, which provides that the Products Policy does not apply to claims arising out of injuries expected or intended by the insured; or
- e. Exclusion M, which provides that the Products Policy does not apply to claims arising out of "medical services" as defined within the Products Policy.

59. Navigators additionally maintains that it has no duty to defend or indemnify Pernix with respect to Count Nine of the Arkansas Lawsuit because the Arkansas Drug Dealer Liability Act, under which that claim was made, specifically provides that “[a] third party, including an insurance company, shall not be required to pay damages awarded under this chapter, nor shall any person be vicariously liable for the act of another, nor shall a third party be made a party to any action brought under this chapter.” Ark. Code Ann. § 16-124-103(c)(2).

60. An actual controversy exists between Navigators and Pernix regarding whether the Products Policy obligates Navigators to defend the Opioid Lawsuits.

61. Navigators is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the Products Policy does not obligate it to defend Pernix in the Opioid Lawsuits.

**COUNT II – NO DUTY TO INDEMNIFY**  
**(Products Policy)**

62. Navigators incorporates by reference the allegations in Paragraphs 1 through 61 above as if fully set forth herein.

63. An actual controversy exists between Navigators and Pernix regarding whether the Products Policy obligates Navigators to indemnify Pernix for judgment in, or settlement of, the Opioid Lawsuits.

64. Navigators is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the Products Policy does not obligate it to indemnify Pernix for any judgment in, or settlement of, the Opioid Lawsuits.

**COUNT III – NO DUTY TO DEFEND**  
**(CGL Policy)**

65. Navigators incorporates by reference the allegations in Paragraphs 1 through 64. above as if fully set forth herein.

66. The Opioid Lawsuits do not seek damages for “bodily injury” caused by an “occurrence” as these terms are defined within the CGL Policy.

67. Instead, the Opioid Lawsuits seek economic losses, restitution, statutory penalties, multiplied damages and equitable relief based upon Pernix’s intentional conduct.

68. Additionally, all of the causes of action within the Opioid Lawsuits arise out of pharmaceutical products designed and/or manufactured by Pernix. Therefore, recovery under the CGL Policy is precluded by Exclusion r., the products-completed operations hazard exclusion.

69. Recovery under the CGL Policy is also precluded by Exclusion s., the health care services exclusion.

70. An actual controversy exists between Navigators and Pernix regarding whether the CGL Policy obligates Navigators to defend the Opioid Lawsuits.

71. Navigators is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the CGL Policy does not obligate it to defend Pernix in the Opioid Lawsuits.

**COUNT IV – NO DUTY TO INDEMNIFY**  
**(CGL Policy)**

72. Navigators incorporates by reference the allegations in Paragraphs 1 through 71 above as if fully set forth herein.

73. An actual controversy exists between Navigators and Pernix regarding whether the CGL Policy obligates Navigators to indemnify Pernix for any judgment in, or settlement of, the Opioid Lawsuits.

74. Navigators is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the CGL Policy does not obligate it to indemnify Pernix in the Opioid Lawsuits.

**COUNT V – NO DUTY TO DEFEND**  
**(Umbrella Policy)**

75. Navigators incorporates by reference the allegations in Paragraphs 1 through 74 above as if fully set forth herein.

76. The Opioid Lawsuits do not seek damages for “bodily injury” arising out of an “occurrence” as these terms are defined by the CGL Policy, which definitions are incorporated by reference into the Umbrella Policy.

77. Instead, the Opioid Lawsuits seek economic losses, restitution, statutory penalties, multiplied damages and equitable relief based upon Pernix’s intentional conduct.

78. Additionally, all of the causes of action within the Opioid Lawsuits arise out of pharmaceutical products designed and/or manufactured by Pernix. Therefore, recovery under the Umbrella Policy is precluded by Exclusion r. of the CGL Policy, the products-completed operations hazard exclusion, which is incorporated by reference into the Umbrella Policy.

79. Recovery under the Umbrella Policy is also precluded by Exclusion s. of the CGL Policy, the health care services exclusion, which is incorporated by reference into the Umbrella Policy.

80. An actual controversy exists between Navigators and Pernix regarding whether the Umbrella Policy obligates Navigators to defend the Opioid Lawsuits.

81. Navigators is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the Umbrella Policy does not obligate it to defend Pernix in the Opioid Lawsuits.

**COUNT VI – NO DUTY TO INDEMNIFY**  
**(Umbrella Policy)**

82. Navigators incorporates by reference the allegations in Paragraphs 1 through 81 above as if fully set forth herein.

83. An actual controversy exists between Navigators and Pernix regarding whether the Umbrella Policy obligates Navigators to indemnify Pernix for any judgment in, or settlement of, the Opioid Lawsuits.

84. Navigators is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the Umbrella Policy does not obligate it to indemnify Pernix for any judgment in, or settlement of, the Opioid Lawsuits.

**COUNT VII– ALLOCATION (IN THE ALTERNATIVE)**

85. Navigators incorporates by reference the allegations in Paragraphs 1 through 84 above as if fully set forth herein.

86. To the extent that any Counts of the Opioid Lawsuits are covered by one or more of the Policies, Navigators is entitled to allocation between covered and uncovered defense and indemnification costs.

**PRAYER FOR RELIEF**

WHEREFORE, Navigators prays that this Honorable Court find and declare the rights and duties of the parties, and specifically find and declare:

- a. That Navigators owes no duty to defend or indemnify Pernix under in the Opioid Lawsuits under the Products Policy.
- b. That Navigators owes no duty to defend or indemnify Pernix under in the Opioid Lawsuits under the CGL Policy.



- c. That Navigators owes no duty to defend or indemnify Pernix under in the Opioid Lawsuits under the Umbrella Policy.
- d. In the alternative, that Navigators is entitled to allocation between covered and uncovered costs.
- e. For all such other and further relief as the Court deems equitably just and proper.

Dated:

Respectfully submitted,

**Segal McCambridge Singer & Mahoney, Ltd.**

By: 

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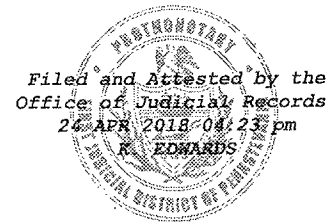
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# **EXHIBIT A**

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UFCW, LOCAL 23 AND EMPLOYERS  
HEALTH FUND,  
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CANONSBURG, PENNSYLVANIA 15317

PLAINTIFF,

V.

ENDO PHARMACEUTICALS, INC.  
1400 ATWATER DRIVE  
MALVERN, PA 19355

AND

ENDO HEALTH SOLUTIONS, INC.  
1400 ATWATER DRIVE  
MALVERN, PA 19355

AND

PURDUE PHARMA, L.P.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND

PURDUE PHARMA, INC.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND

COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY

CASE No.

CIVIL ACTION

JURY TRIAL DEMANDED

PURDUE FREDERICK COMPANY, INC.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND

ABBOTT LABORATORIES, INC.  
100 ABBOTT PARK ROAD  
ABBOTT PARK, IL 60064

AND

JANSSEN PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933

AND

ORTHO-McNEIL-JANSSEN  
PHARMACEUTICALS, INC. N/K/A JANSSEN  
PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

JANSSEN PHARMACEUTICA, INC. N/K/A  
JANSSEN PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

ALLERGAN, PLC F/K/A ACTAVIS PLC  
5 GIRALDA FARMS  
MADISON, NJ 07940

AND

ACTAVIS, INC. F/K/A WATSON  
PHARMACEUTICALS, INC.  
5 GIRALDA FARMS  
MADISON, NJ 07940

AND

WATSON LABORATORIES, INC.  
132 BUSINESS CENTER DRIVE  
CORONA, CA 92880-1724

AND

ACTAVIS, LLC  
MORRIS CORPORATE CENTER III  
400 INTERPACE PARKWAY  
PARSIPPANY, NJ 07054-1120

AND

ACTAVIS PHARMA, INC. F/K/A WATSON  
PHARMA, INC.  
MORRIS CORPORATE CENTER III  
400 INTERPACE PARKWAY  
PARSIPPANY, NJ 07054

AND

MALLINCKRODT, INC.  
675 JAMES S. McDONNELL BLVD.,  
HAZELWOOD, MO 63042

AND

ABBVIE, INC.  
1 N. WAUKEGAN ROAD  
NORTH CHICAGO, IL 60064

AND

ZOGENIX, INC.  
12400 HIGH BLUFF DRIVE, SUITE 650  
SAN DIEGO, CA 92130

AND

PERNIX THERAPEUTICS HOLDINGS, INC.  
10 NORTH PARK PLACE, SUITE 201  
MORRISTOWN, NJ 07960

AND

WEST-WARD PHARMACEUTICALS CORP.  
401 INDUSTRIAL WAY WEST  
EATONTOWN, NJ 07724

AND

SHIONOGI, INC.  
300 CAMPUS DRIVE  
FLORHAM PARK, NJ 07932

AND

VALIDUS PHARMACEUTICALS, LLC  
119 CHERRY HILL ROAD, SUITE 310  
PARSIPPANY, NJ 07054

DEFENDANTS.

**NOTICE TO DEFEND**

**NOTICE:** You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objection to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

**YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.**

Philadelphia Bar Association, Lawyer Referral and Information Service  
1101 Market Street, Philadelphia, PA 19107 / (215) 238-6333

**AVISO:** Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las páginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la

demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades o otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELÉFONO A LA OFICINA CUYA DIRECCIÓN SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACIÓN DE LICENCIADOS DE FILADELFIA  
Servicio De Referencia E Información Legal  
1101 Market Street, Philadelphia, PA 19107 / (215) 238-6333

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[hweinstein@anapolweiss.com](mailto:hweinstein@anapolweiss.com)  
[cflaherty@anapolweiss.com](mailto:cflaherty@anapolweiss.com)

ATTORNEYS FOR PLAINTIFF

UFCW, LOCAL 23 AND EMPLOYERS  
HEALTH FUND,  
345 SOUTHPOINTE BLVD., SUITE 200  
CANONSBURG, PENNSYLVANIA 15317

COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY

CASE No.

PLAINTIFF,

CIVIL ACTION

V.

JURY TRIAL DEMANDED

ENDO PHARMACEUTICALS, INC.  
1400 ATWATER DRIVE  
MALVERN, PA 19355

AND

ENDO HEALTH SOLUTIONS, INC.  
1400 ATWATER DRIVE  
MALVERN, PA 19355

AND

PURDUE PHARMA, L.P.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND

PURDUE PHARMA, INC.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND



PURDUE FREDERICK COMPANY, INC.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND

ABBOTT LABORATORIES, INC.  
100 ABBOTT PARK ROAD  
ABBOTT PARK, IL 60064

AND

JANSSEN PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

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NEW BRUNSWICK, NJ 08933

AND

ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC. N/K/A JANSSEN  
PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

JANSSEN PHARMACEUTICA, INC. N/K/A  
JANSSEN PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

ALLERGAN, PLC F/K/A ACTAVIS PLC  
5 GIRALDA FARMS  
MADISON, NJ 07940

AND

ACTAVIS, INC. F/K/A WATSON  
PHARMACEUTICALS, INC.  
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AND

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132 BUSINESS CENTER DRIVE  
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AND

ACTAVIS, LLC  
MORRIS CORPORATE CENTER III  
400 INTERPACE PARKWAY  
PARSIPPANY, NJ 07054-1120

AND

ACTAVIS PHARMA, INC. F/K/A WATSON  
PHARMA, INC.  
MORRIS CORPORATE CENTER III  
400 INTERPACE PARKWAY  
PARSIPPANY, NJ 07054

AND

MALLINCKRODT, INC.  
675 JAMES S. McDONNELL BLVD.,  
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AND

ABBVIE, INC.  
1 N. WAUKEGAN ROAD  
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AND

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AND

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10 NORTH PARK PLACE, SUITE 201  
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AND

WEST-WARD PHARMACEUTICALS CORP.  
401 INDUSTRIAL WAY WEST  
EATONTOWN, NJ 07724

AND

SHIONOGI, INC.  
300 CAMPUS DRIVE  
FLORHAM PARK, NJ 07932

AND

VALIDUS PHARMACEUTICALS, LLC  
119 CHERRY HILL ROAD, SUITE 310  
PARSIPPANY, NJ 07054

DEFENDANTS.

# COMPLAINT

Plaintiff UFCW, Local 23 and Employers Health Fund (the “FUND”), by and through its attorneys, ANAPOL WEISS, hereby brings this civil action seeking relief from Defendants Abbott Laboratories, Inc. (“ABBOTT”); Allergan, PLC F/K/A Actavis PLC, Actavis, Inc. F/K/A Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis, LLC, and Actavis Pharma, Inc. F/K/A Watson Pharma, Inc. (collectively, “ALLERGAN”); Endo Pharmaceuticals, Inc., Endo Health Solutions, Inc. (collectively, “ENDO”); Janssen Pharmaceuticals, Inc., Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals N/K/A Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc. (collectively, “JOHNSON & JOHNSON”); Purdue Pharma, L.P., Purdue Pharma, Inc., Purdue Frederick Company, Inc. (collectively, “PURDUE”), Mallinckrodt Inc., (“MALLINCKRODT”), AbbVie, Inc. (“ABBVIE”), Zogenix, Inc. (“ZOGENIX”), Pernix

Therapeutics Holdings, Inc. (“PERNIX”), West-Ward Pharmaceuticals Corp. (“WEST-WARD”), Shionogi, Inc. (“SHIONOGI”), and Validus Pharmaceuticals, LLC (“VALIDUS”),<sup>1</sup> and avers as follows upon the personal knowledge of the undersigned and their own acts and experiences, and as to all other matters, upon information and belief, including investigation conducted by its attorneys:

### INTRODUCTION

1. Despite well-recognized legal principles requiring DEFENDANTS to be truthful in their representations and marketing activities regarding their opioid-based pharmaceuticals, DEFENDANTS have engaged in an intentional, decades-long pattern of deceptive and misrepresentative conduct that has impermissibly obfuscated the grave medical risks associated with utilizing opioids pharmaceuticals created and/or marketed by DEFENDANTS to treat long-term and/or chronic pain<sup>2</sup> and similar medical conditions.

2. This unconscionable behavior has created a national epidemic of catastrophic proportions, with drug overdose now recognized as the leading cause of death for all Americans under 50.<sup>3</sup> In 2016 alone, approximately 4,642 overdose-related deaths were reported in the Commonwealth of Pennsylvania, meaning that an average of 13 Pennsylvanians died every day of the year (and with the presence of opioids confirmed in at least 85 percent of those incidents).<sup>4</sup> In Philadelphia City and County, alone, there were some 907 overdose-related deaths in 2016 (again, with the presence of opioids confirmed in

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<sup>1</sup> These entities will be collectively referred to as “DEFENDANTS” where appropriate and expedient.

<sup>2</sup> As utilized in this Complaint, “chronic pain” refers to non-cancer-based pain lasting three months, or longer.

<sup>3</sup> See, e.g., Sheila Kaplan, “C.D.C. Reports a Record Jump in Drug Overdose Deaths Last Year,” THE NEW YORK TIMES, (November 3, 2017), available at <https://goo.gl/KaUFqn>.

<sup>4</sup> See, e.g., U.S. Drug Enforcement Agency & Univ. of Pittsburgh, “Analysis of Overdose Deaths in Pennsylvania, 2016,” (July 2017), at 5, available at <https://goo.gl/i89z7x>.

more than 80 percent of those incidents).<sup>5</sup> Statewide and in Philadelphia, prescription opioids accounted for approximately 25 and 22 percent of those deaths, respectively.<sup>6</sup>

3. Even worse, overdose-related deaths increased in both the Commonwealth and Philadelphia by 27 and 29 percent, respectively, between 2015 and 2016.<sup>7</sup> These unprecedented spikes in overdose-related deaths tellingly coincide with equally unparalleled increases in opioid prescriptions: between 1999 and 2014, sales of prescription opioids quadrupled with a concomitant increase in the number of deaths related to prescription opioids.<sup>8</sup> Publicly available data indicates that abuse of prescription opioids is a contributing risk factor in the use of illegal narcotics (*e.g.*, heroin) and addiction.<sup>9</sup>

4. Despite DEFENDANTS' duty to represent truthfully (*i.e.*, not to misrepresent) the nature and efficacy of its pharmaceuticals, DEFENDANTS made misrepresentations about their drugs simply to earn more money and accumulate larger profits. DEFENDANTS' focus on profitability callously ignored (and ignores) the truth borne out in the grim statistics recited above. This reality is in large part, the natural consequences at DEFENDANTS' activities described herein.<sup>10</sup>

<sup>5</sup> See, *e.g.*, Philadelphia Dep't of Pub. Health, "2016 Overdoses From Opioids in Philadelphia," CHART, 2:7 (April 2017), at 1, available at <https://goo.gl/wg1TYL>.

<sup>6</sup> See, *e.g.*, *supra* n.4 at 5, 90.

<sup>7</sup> *Id.*

<sup>8</sup> See, *e.g.*, Centers for Disease Control and Prevention, "Opioid Overdose: Prescribing Data," (August 30, 2017), available at <https://goo.gl/fYuS2o>.

<sup>9</sup> See, *e.g.*, Wilson M. Compton, M.D., *et al.*, "Relationship between Nonmedical Prescription-Opioid Use and Heroin Use," N. ENGL. J. MED. 374:2, at 160-61 (January 14, 2016) ("Available data indicate that the nonmedical use of prescription opioids is a strong risk factor for heroin use. . . . The transition from nonmedical use of prescription opioids to heroin use appears to be part of the progression of addiction . . . primarily among persons with frequent nonmedical use and those with prescription opioid abuse or dependence.").

<sup>10</sup> See, *e.g.*, Susan Okie, "A Flood of Opioids, a Rising Tide of Deaths," 363 NEW ENGL. J. MED. 1981 (2010) (concluding that opioid overdose deaths and prescriptions for opioids both increased roughly by 10-fold from 1990 to 2007).

5. Overall, DEFENDANTS have committed civil insurance fraud<sup>11</sup> and violated the common law of Pennsylvania. By flagrantly misrepresenting the efficacy of their own products and impermissibly minimizing the risks associated with the use of those same products, DEFENDANTS have caused significant and ascertainable harm to the FUND and its participants, retirees, and their dependents.

### **JURISDICTION AND VENUE**

6. This action has been commenced within the original subject matter jurisdiction of the Philadelphia County Court of Common Pleas pursuant to 42 P.S. § 931.

7. Overall, personal jurisdiction is proper in light of the general and specific contacts DEFENDANTS maintain with the Commonwealth of Pennsylvania. DEFENDANTS regularly and systematically transact business within Pennsylvania pursuant to 42 Pa.C.S. §§ 5322(a)(1)(i)-(v). Furthermore, ENDO maintains its principal places of business within the Commonwealth of Pennsylvania, and Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania. Thus, personal jurisdiction is properly exercised over DEFENDANTS.

8. Venue is proper in this Court pursuant to PA. R. CIV. P. 1006 as Philadelphia County is a county in which DEFENDANTS regularly and systematically conducts business and a county in which a substantial part of the events giving rise to the claims occurred.

### **THE PARTIES**

#### **PLAINTIFF (FUND):**

9. Plaintiff FUND is an employee benefit plan, with an office and principal place of business located at 345 Southpointe Blvd., Suite 200, Canonsburg, PA 15317, and is thus a citizen of Pennsylvania. The FUND was established with the explicit purpose of

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<sup>11</sup> 18 Pa.C.S. §4117(g).

providing health and welfare benefits for covered lives, including employees and former employees (and their dependents) who pay into the FUND, and are represented by United Food & Commercial Workers Local 23 (“Local 23”) for purposes of collective bargaining. These benefits include, but are not limited to, a range of prescription drug benefit plans. Pursuant to the administration and management of these various plans and at all times relevant hereto, the FUND, through managed care administrators and others, purchased and purchases prescription drugs for the FUND’s participants, retirees, and their dependents, or reimbursed the aforesaid individuals for their prescription drug purchases.

**ENDO:**

10. Defendant Endo Health Solutions, Inc. is a corporation organized under the laws of the State of Delaware and with its principal place of business and corporate headquarters located at 1400 Atwater Drive, Malvern, PA 19355.

11. Defendant Endo Pharmaceuticals Inc. is a corporation incorporated under the laws of the State of Delaware and with its principal place of business and corporate headquarters located at 1400 Atwater Drive, Malvern, PA 19355. It is a wholly owned subsidiary of Endo Health Solutions, Inc.

12. Upon information and belief, ENDO has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Opana ER** (oxymorphone hydrochloride): Schedule II opioid agonist extended-release tablet first approved in 2006 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate.” Prior to April 2014, Opana ER was indicated for the “relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.”

- b. **Percodan** (oxycodone hydrochloride and aspirin): Schedule II opioid agonist tablet first approved in 1950 and first marketed by ENDO in 2004 and indicated for the “management of moderate to moderately severe pain.”
- c. **Percocet/Endocet**<sup>12</sup> (oxycodone and acetaminophen): Schedule II opioid agonist tablets first approved in 1999 and first marketed by ENDO in 2006 and indicated for the “relief of moderate to moderately severe pain.”

13. At all times relevant hereto, ENDO through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Opana ER, Percodan, Percocet, and Endocet (hereinafter, collectively “ENDO Opioids”) throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**PURDUE:**

14. Defendant Purdue Pharma, L.P., is a limited partnership organized under the laws of the State of Delaware, and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.

15. Defendant Purdue Pharma, Inc., is a corporation organized under the laws of the State of Delaware, and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.

16. Defendant Purdue Frederick Company, Inc., is a corporation organized under the laws of the State of Delaware, and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.

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<sup>12</sup> Although marketed in different dosages, these two drugs are functionally identical.



17. Upon information and belief, PURDUE has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **OxyContin** (oxycodone hydrochloride): Schedule II opioid agonist extended-release tablet first approved in 1995 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Prior to April 2014, OxyContin was indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.
- b. **Dilaudid/Dilaudid-5<sup>13</sup>** (hydromorphone hydrochloride): Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the management of pain in patients where an opioid analgesic is appropriate.
- c. **Butrans** (buprenorphine): Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Prior to April 2014, Butrans was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”
- d. **Hysingla ER** (hydrocodone bitrate): Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate.
- e. **Ryzolt** (tramadol hydrochloride): Schedule II opioid agonist extended-release tablet first approved in December 2008 and indicated for the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time.

18. At all times relevant hereto, PURDUE through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured,

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<sup>13</sup> “Dilaudid” refers to the tablet version of this product, while “Dilaudid-5” refers to the oral solution.

advertised, promoted, marketed, sold, and distributed OxyContin, Dilaudid/Dilaudid-5, Butrans, Hysingla ER, and Ryzolt (hereinafter, collectively “PURDUE Opioids”) throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**ABBOTT:**

19. Defendant Abbott Laboratories, Inc., is a corporation incorporated under the laws of the State of Illinois and with its principal place of business and corporate headquarters located at 100 Abbott Park Road, Abbott Park, Illinois 60064.

20. Upon information and belief, ABBOTT entered in to a co-promotion agreement with PURDUE in 1996. ABBOTT actively marketed PURDUE Opioids pursuant to that agreement from 1996 to 2002 in collaboration and conjunction with the concomitant efforts of PURDUE. Thereafter, ABBOTT received residual payments on the sale of PURDUE Opioids until 2006.

21. At all times relevant hereto, ABBOTT through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly advertised, promoted, marketed, sold, and distributed PURDUE Opioids throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**JOHNSON & JOHNSON:**

22. Defendant Johnson & Johnson is a corporation organized under the laws of the State of New Jersey and with its principal place of business and corporate headquarters located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

23. Defendant Janssen Pharmaceuticals, Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, and with its principal place of business and

corporate headquarters located at 1125 Bear Tavern Road, Titusville, NJ 08560. It is a wholly owned subsidiary of Johnson & Johnson.

24. Defendant Ortho-McNeil-Janssen Pharmaceuticals N/K/A Janssen Pharmaceuticals, Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, and with its principal place of business and corporate headquarters located at 1125 Bear Tavern Road, Titusville, NJ 08560.

25. Defendant Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, and with its principal place of business and corporate headquarters located at 1125 Bear Tavern Road, Titusville, NJ 08560.

26. Upon information and belief, JOHNSON & JOHNSON has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Nucynta** (tapentadol): Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the “relief of moderate to severe acute pain in patients 18 years of age or older.”
- b. **Nucynta ER** (tapentadol extended release): Schedule II opioid agonist tablet first approved in 2011 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, Nucynta ER was indicated for the “management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults.” The DPN indication was added in August 2012.
- c. **Ultram** (tramadol hydrochloride): Schedule II opioid agonist tablet first approved in 1995 and indicated for the management of moderate to moderately severe pain in adults.
- d. **Ultram ER** (tramadol hydrochloride): Schedule II opioid agonist extended-release tablet first approved in September 2005 and

indicated for the management of pain severe enough to require daily around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

- e. **Duragesic** (fentanyl): Schedule II opioid agonist transdermal patch first approved in August 1990 and indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

27. At all times relevant hereto, JOHNSON & JOHNSON through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Nucynta, Nucynta ER, Ultram, Ultram ER, and Duragesic (hereinafter, collectively “J&J Opioids”), throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**ALLERGAN:**

28. Defendant Allergan, PLC F/K/A Actavis PLC, is a public limited company organized under the laws of the Republic of Ireland, with its corporate headquarters and principal place of business located at 5 Giralda Farms, Madison, NJ 07940.

29. Defendant Actavis, Inc. F/K/A Watson Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Nevada with its corporate headquarters and principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

30. Defendant Watson Laboratories, Inc. is a corporation organized under the laws of the State of Nevada and with its corporate headquarters and principal place of business located at 311 Bonnie Circle, Corona, CA 92880.

31. Defendant Actavis, LLC is a limited liability corporation organized under the laws of the State of Delaware and with its corporate headquarters and principal place of

business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

32. Defendant Actavis Pharma, Inc. F/K/A Watson Pharma, Inc. is a corporation organized under the laws of the State of Delaware, and with its principal place of business and corporate headquarters located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

33. All of the above-mentioned entities are owned by Allergan, PLC, which utilizes them to develop, market, advertise, promote, and sell pharmaceuticals in the Commonwealth of Pennsylvania. Upon information and belief, Allergan, PLC controls, directs, and/or administrates these marketing and sales efforts, with all resulting profits accruing, ultimately, to the benefit of Allergan, PLC.

34. Upon information and belief, ALLERGAN has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Kadian** (morphine sulfate extended release): Schedule II opioid agonist capsule first approved in 1996 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, Kadian was indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

35. ALLERGAN acquired the rights to Kadian in December 2008, and began marketing, advertising, promoting, and selling Kadian in 2009.

36. At all times relevant hereto, ALLERGAN through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Kadian throughout the

Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**MALLINCKRODT**

37. Defendant Mallinckrodt Inc. is a domestic corporation organized under the laws of the State of Delaware, and with its corporate headquarters located at 675 James S. McDonnell Boulevard, Hazelwood, Missouri 63042.

38. Upon information and belief MALLINCKRODT has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Exalgo** (hydromorphone hydrochloride): Schedule II opioid agonist extended-release tablet first approved in March 2010 and indicated for the management of pain in opioid-tolerant patients severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

39. At all times relevant hereto, MALLINCKRODT through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Exalgo throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**ABBVIE**

40. AbbVie, Inc. is a corporation organized under the laws of the State of Delaware, and with its corporate headquarters located at 1 North Waukegan Road, North Chicago, Illinois 60064.

41. Specifically, ABBVIE is the corporate remainder of ABBOTT taking the decision to essentially divide its corporate business, and spin-off its sales of pharmaceuticals

(including opioids) into a separate corporate entity. ABBVIE is the resulting entity, and has carried on ABBOTT's marketing and manufacturing undertakings since January 1, 2013.

42. Upon information and belief ABBVIE has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Vicodin/Vicodin ES**<sup>14</sup> (hydrocodone bitartrate and acetaminophen): Schedule II opioid agonist tablet first approved in 1984 and 1991 (respectively) and both indicated for the relief of moderate to moderately severe pain.
- b. **Vicoprofen** (hydrocodone bitartrate and ibuprofen): Schedule II opioid agonist tablet first approved in 1997 and indicated for the short-term management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

43. At all times relevant hereto, MALLINCKRODT through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Vicodin/Vicodin ES and Vicoprofen throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

#### **ZOGENIX & PERNIX**

44. Pernix Therapeutics Holdings, Inc. is a corporation organized under the laws of the State of Maryland, and with its corporate headquarters located at 10 North Park Place, Suite 201, Morristown, New Jersey 07960.

45. Zogenix, Inc. is a corporation organized under the laws of the State of Delaware, and with its corporate headquarters located at 12400 High Bluff Drive, San Diego, California 92130.

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<sup>14</sup> Although marketed in different dosages, these two drugs are functionally identical.

46. Upon information and belief PERNIX and ZOGENIX have both been (and PERNIX currently still is) developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Zohydro ER** (hydrocodone bitartrate): Schedule II opioid agonist extended-release tablet first approved in 2013 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

47. Specifically, ZOGENIX originally obtained FDA approval for Zohydro ER in 2013, but thereafter sold their interest in the product to PERNIX in 2015. Upon information and belief, both ZOGENIX and PERNIX participated in the collusive marketing practices detailed throughout this complaint during their respective periods of ownership and control of Zohydro ER.

48. At all times relevant hereto, ZOGENIX and PERNIX through their respective corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Zohydro ER throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

#### **WEST-WARD**

49. West-Ward Pharmaceuticals Corp. is a corporation organized under the laws of the State of Delaware, and with its principal place of business located at 401 Industrial Way West, Eatontown, New Jersey 07724.



50. Upon information and belief WEST-WARD has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Roxicet** (oxycodone hydrochloride and acetaminophen): Schedule II opioid agonist tablet first approved in 1980 and indicated for the relief of moderate to moderately severe pain.

51. Roxicet was originally manufactured and marketed by Roxane Laboratories, Inc., but WEST-WARD's parent company (Hikma) acquired Roxane in 2015 and merged Roxane into WEST-WARD (including ownership and control of Roxicet). Thus, WEST-WARD is both the successor-in-interest to Roxane and the current owner of Roxicet.

52. At all times relevant hereto, WEST-WARD through its corporate subsidiaries, authorized agents, servants, employees, and/or representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Zohydro ER throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND, and its participants, retirees, and their dependents.

#### SHIONOGI

53. Shionogi Inc. is organized under the laws of the State of Delaware, and with its corporate headquarters located at 300 Campus Drive, Florham Park, New Jersey 07932.

54. Upon information and belief SHIONOGI has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Xodol** (hydrocodone bitartrate and acetaminophen): Schedule II opioid agonist tablet first approved in 2006 and indicated for the relief of moderate to moderately severe pain.

55. At all times relevant hereto, SHIONOGI through its corporate subsidiaries, authorized agents, servants, employees, and/or representatives regularly manufactured,

advertised, promoted, marketed, sold, and distributed Xodol throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

### **VALIDUS**

56. Validus Pharmaceuticals, LLC is a limited liability company organized under the laws of the State of Delaware, and with its corporate headquarters located at 119 Cherry Hill Road, Suite 310, Parsippany, New Jersey 07054.

57. Upon information and belief VALIDUS has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Demerol** (meperidine hydrochloride): Schedule II opioid agonist injection first approved in 1942 and indicated for preoperative medication, support of anesthesia, for obstetrical analgesia, and for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

58. At all times relevant hereto, VALIDUS through its corporate subsidiaries, authorized agents, servants, employees, and/or representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Demerol throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

### **FACTUAL BACKGROUND**

#### **A. Opioids Have Limited Medically Approved Uses and Pose Severe Risks (Including Death and Addiction), Even Used Appropriately.**

59. The term “opioid” refers to and includes all natural, synthetic, and semi-synthetic substances that bind to and interact with the opioid receptors in the human brain. This civil action implicates a specific subclass of opioids known as “opioid agonists,” which principally have an analgesic effect when taken for therapeutic purposes (*i.e.*, the relief of

pain).<sup>15</sup> Pharmacologically, opioids interact with receptors located in the human brain and spinal cord, and are an effective option in the treatment of acute short-term pain (*e.g.*, surgery, traumatic injuries, and/or cancer) and the provision of end-of-life care.<sup>16</sup>

60. Despite these limited acceptable uses, opioids are essentially identical to narcotics like heroin and opium, in terms of pharmacological effect and the dangerously high risks for abuse,<sup>17</sup> development of dependence/tolerance, and addiction.<sup>18</sup> The abuse (and even the mere *use*) of opioids is also associated with the potential for severe physical side effects, including respiratory depression, coma, and death.<sup>19</sup>

61. Individuals using and/or abusing opioids in the long-term eventually develop tolerance (and, therefore, require ever-increasing dosages to continue to achieve the desired analgesic effect).<sup>20</sup> The diminishing returns of treatment make overdoses insidiously common,<sup>21</sup> while ceasing the use of opioids, altogether, risks severe withdrawal symptoms.

<sup>15</sup> See, *e.g.*, Freye, Enno, “Part II. Mechanism of action of opioids and clinical effects,” *Opioids in Medicine: A Comprehensive Review on the Mode of Action and the Use of Analgesics in Different Clinical Pain States*, p. 85 (2008) (“Opioid is a general term that includes naturally occurring, semi-synthetic, and synthetic drugs, which produce their effects by combining with opioid receptors . . .”).

<sup>16</sup> See, *e.g.*, Nathaniel Katz, “Opioids: After Thousands of Years, Still Getting to Know You,” 23(4) CLIN J. PAIN 303 (2007); Roger Chou, *et al.*, “Research Gaps on Use of Opioids for Chronic Noncancer Pain,” 10(2) J. PAIN 147 (2009).

<sup>17</sup> See, *e.g.*, Wilson M. Compton & Nora D. Volkow, “Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies,” 81(2) DRUG & ALCOHOL DEPENDENCE 103, 106 (2006) (“[A] potential side effect from chronic use [of opioids] can be abuse and addiction . . . . In fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena.”).

<sup>18</sup> As used throughout this Complaint, the term “addiction” refers to the full spectrum of “substance abuse disorders” identified in the authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) (“DSM-V”), and encompasses behavior ranging from abuse/misuse of drugs, through physical and/or mental dependence, to addiction.

<sup>19</sup> See, *e.g.*, Letter from Janet Woodcock, M.D. to Andrew Kolodny, MD RE: Docket No. FDA-2012-P-0818 (September 10, 2013), at 2, available at <https://goo.gl/gfidBu> (“Even proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.”).

<sup>20</sup> See, *e.g.*, Mitchell H. Katz, “Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith,” 170(16) ARCHIVES OF INTERNAL MED. 1422 (2010) (describing doses that are “frighteningly high”).

<sup>21</sup> See, *e.g.*, “Opioid Overdose,” CENTERS FOR DISEASE CONTROL AND PREVENTION, available at <https://www.cdc.gov/drugoverdose/index.html> (reporting that opioid-related overdoses accounted for more than 33,000 deaths in 2015, nearly half involving prescription drugs).

Given the volatile potential for addiction and physical harm associated with even medically proper use, opioids have been regulated as controlled substances for decades.

62. Although generally effective in the treatment of short-term ailments, no controlled studies have ever established the efficacy (or safety) of using opioids in the treatment of chronic pain or other long-term conditions. Indeed, medical and pharmacological articles and studies produced during the 1970s, 1980s, and 1990s indicated a growing scientific consensus that opioids should be discouraged (or even prohibited), in the treatment of chronic pain:

The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuated reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.<sup>22</sup>

63. Continuing through until the present, medical evidence continues to establish that the long-term use of opioids produces rapidly diminishing analgesic benefits (if any)<sup>23</sup>

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<sup>22</sup> Russell K Portenoy, "Opioid Therapy for Chronic Nonmalignant Pain: Current Status," 1 PROGRESS IN PAIN RES. & MGMT. 247 (1994).

<sup>23</sup> See, e.g., Andrea D. Furlan, *et al.*, "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," 174(11) CAN. MED. ASS'N J. 1589 (2006); Eriksen J., *et al.*, "Critical issues on opioids in chronic non-cancer pain," 125 PAIN 172, 172-79 (2006) (concluding that chronic pain patients taking opioids self-scored themselves lower in terms of body pain, physical function, mental function, social function, and vitality compared to non-opioid patients); Dillie K.S., *et al.*, "Quality of life associated with daily opioid therapy in a primary care chronic pain sample," 21 J. AM. BD. FAM. MED. 108, 108-17 (2008).

and diminishes patients' overall health.<sup>24</sup> Indeed, prior to the acts of DEFENDANTS complained of herein "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids."<sup>25</sup>

64. The widely recognized therapeutic restrictions discussed above significantly limit (or, *should* limit) the available Patient Population Market<sup>26</sup> for the marketing and sale of opioids. Put simply, the medical consensus that opioids are ineffective (and, in fact, gravely dangerous) when used to treat long-term conditions and/or chronic pain was nothing more than an economically inconvenient truth to the DEFENDANTS.

**B. DEFENDANTS' Marketing Campaigns Proliferated Dangerous Misperceptions That "Chronic Opioid Therapy" is Effective and Safe.**

65. Solely in the service of achieving dramatic growth in sales and revenue, DEFENDANTS individually (and, in many instances, cooperatively) undertook concerted efforts to alter the medically accepted standard of care regarding opioids. In particular, DEFENDANTS were concerned with persuading both patients and doctors that opioids are effective and safe in the treatment of common, chronic pain conditions (*e.g.*, headaches, joint pain/arthritis, back/knee pain, *etc.*) and similar medical conditions (hereinafter, "chronic opioid therapy").

66. DEFENDANTS created an entire market from whole cloth by promoting the false efficacy of chronic opioid therapy. DEFENDANTS also endeavored to impermissibly minimize and obfuscate the risks associated with opioid use, including but not limited to addiction/dependence, development of tolerance, infection, and death. Overall,

<sup>24</sup> See, *e.g.*, Andrea Rubenstein, "Are we making pain patients worse?" SONOMA MEDICINE (Fall 2009), available at <https://goo.gl/SpqD2P> ("[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.").

<sup>25</sup> Igor Kissin, "Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?", 6 J. PAIN RESEARCH 513, 514 (2013).

<sup>26</sup> Term of art referring to the projected market (*i.e.*, potential patients) for various pharmaceutical products.

DEFENDANTS valued profit more than the public health, and were concerned with safeguarding their bottom line, as opposed to the well-being of their Pennsylvania patients and customers, including the FUND.

67. DEFENDANTS shared a purpose in undertaking their respective campaigns of disinformation, and their methods bespeak certain commonalities as well. Individually and collectively, DEFENDANTS engaged in behaviors that created and proliferated dangerously misleading impressions amongst doctors and patients, which: (i) misrepresented opioids as generally safe for use by most patients; (ii) misrepresented and exaggerated the efficacy of “chronic opioid therapy;” (iii) impermissibly minimized the risks of addiction/dependence/tolerance posed by the use of opioids, including creation and proliferation of the concept of “pseudoaddiction”;<sup>27</sup> (iv) misrepresented the ability of so-called “screening tools” to identify patients at risk of addiction/dependence; (v) misrepresented and impermissibly minimized the grave risks of taking ever-higher doses of opioids to maintain long-term pain relief; (vi) misleadingly portrayed and enlarged the risks associated with opioid competitors, such as non-steroidal anti-inflammatory drugs (“NSAIDs”); and (vii) misrepresented that chronic opioid therapy permits patients to resume their regular lives, improves functionality, and/or improves overall quality of life.

68. Beginning in the late 1990s and continuing until the present, DEFENDANTS engaged in deceptive, unfair, and misleading campaigns to reverse the

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<sup>27</sup> This insidious term was originally coined in a 1989 article suggesting that patients exhibiting behaviors typically associated with opioid addiction were actually suffering from “pseudoaddiction” due to medical undertreatment of patients’ pain. *See, e.g.*, Marion S. Greene & R. Andrew Chambers, “Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature,” *CURR. ADDICTION REP.* (2015) 2(4), at 310-17, *available at* <https://goo.gl/Cqf5UK>. In recent years, this concept has been largely discredited by the medical and academic communities. *Id.* (“Pseudoaddiction is a quarter-century-old concept that has not been empirically verified. . . . The reliability of this conceptualization seems to hinge on the assumption that addiction and pain do not co-occur. . . . However, it is not the case that pain and addiction are mutually exclusive conditions, and no clear evidence exists that having pain protects against the genesis or expression of addiction.”).

popular and medical understanding that opioids are inappropriate for the treatment of long-term and/or chronic pain. To accomplish this wholesale reversal, DEFENDANTS undertook numerous initiatives either directly, or through their agents, employees, servants, and/or representatives, including but not limited to:

- a. developing and disseminating seemingly truthful, purportedly educational materials and advertisements that misrepresented the risks, benefits, and superiority of DEFENDANTS' opioids and chronic opioid therapy;
- b. deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the risks, benefits, and superiority of DEFENDANTS' opioids and chronic opioid therapy;
- c. recruiting, funding, assisting, encouraging, and/or directing third-party, seemingly neutral physicians to act as paid speakers on behalf of DEFENDANTS' opioids and chronic opioid therapy, and to deliver scripted talks, draft misleading studies, present deceptive and misleading continuing medical education programs ("CMEs"), and serve on the boards and committees of professional societies and patient advocacy groups that promulgate guidelines supporting the use of opioids and chronic opioid therapy, (hereinafter, "key opinion leaders" or "KOLs"), including but not limited to David Haddox, Lynn R. Webster, Russell Portenoy, Kathleen Foley, Christine A. Miaskowski, Michael J. Brennan, Perry Fine, Scott Fishman, and Lisa Weiss; and
- d. funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (hereinafter, "Front Groups") that developed educational materials and treatment guidelines that were distributed by, or with assistance from, DEFENDANTS, which urged physicians to prescribe (and patients to use) DEFENDANTS' opioids, or to otherwise utilize chronic opioid therapy.

69. Although the efforts and purpose were common amongst DEFENDANTS, many of their individual actions also bear appropriately individual scrutiny.

i. ENDO

70. ENDO's misleading course of conduct that is generally described above was pervasive and focused primarily on the promotion of Opana ER (although upon information

and belief, ENDO's marketing efforts extended to and included *all* of the ENDO Opioids identified above). Upon information and belief, between 2007 and 2013, ENDO spent between \$3 million and \$10 million each quarter to promote the sales of ENDO Opioids.

71. ENDO's dissemination of misleading materials included branded and non-branded books and pamphlets that were held out as nominatively medical and/or scientific (but, in fact, flagrantly misrepresented accepted medical science regarding chronic opioid therapy and were intended solely to drum-up sales of ENDO Opioids).

72. One such publication was the 2007 book *Avoiding Opioid Abuse While Managing Pain*, which erroneously claims that "[o]pioids offer safe, effective treatment for many chronic pain conditions and pose little risk for addiction for most patients who take them to control pain."<sup>28</sup> The same publication also dangerously emphasizes that aberrant and/or drug-seeking behaviors (*i.e.*, potential evidence of addiction) in patients prescribed opioids should be regarded as evidence of "pseudoaddiction" and that increasing dosages should be the first clinical response. It also makes erroneous claims regarding the efficacy of chronic opioid therapy and gravely misrepresents chronic opioid therapy as a moral imperative on par with a human's ongoing need for sustenance.<sup>29</sup> Upon information and belief, Plaintiff avers that ENDO provided research and financial support and assisted in the distribution of *Avoiding Opioid Abuse While Managing Pain*, as well as providing consulting fees, *honoraria*, or other recompense to its authors and editors.

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<sup>28</sup> See, e.g., Lynn R. Webster, MD & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*, (2007), relevant excerpt available at <https://goo.gl/K8Rx9h>.

<sup>29</sup> *Id.* ("Managing treatment with pharmaceutical analgesics is similar to managing an eating disorder. A person with problems managing food intake cannot solve the problem with abstinence, because eating is necessary for survival. . . . Similarly, society cannot eliminate the use of opioids, even though they can harm some consumers.").



73. ENDO also supported the publication and distribution of a pamphlet titled “Understanding Your Pain: Taking Oral Opioid Analgesics,” which makes outlandish claims along similar claims. In sum, the pamphlet: (i) implies that addiction is not related to the use of opioids, stating that “[a]ddicts take opioids for other reasons [other than pain relief], such as unbearable emotional problems” and that patients taking opioids for the management of pain are not generally at risk of addiction;<sup>30</sup> (ii) misstates the therapeutic limits of chronic opioid therapy, recklessly claiming that such dosages can merely be increased without limitation or consequence;<sup>31</sup> (iii) encourages patients to take pre-emptive opioid doses, advising that patients should “[k]eep on top of [their] pain—don’t wait until pain becomes severe to take your medicine;”<sup>32</sup> and (iv) advises patients to consider taking both long-acting opioids and short-acting opioids in conjunction with one another.<sup>33</sup>

74. Upon information and belief, Plaintiff avers that ENDO provided research and financial support and assisted in the distribution of “Understanding Your Pain: Taking Oral Opioid Analgesics,” as well as providing consulting fees, *honoraria*, or other recompense to its authors and editors.

75. ENDO also provided material, financial, and distributive support in the drafting, publication, and dissemination of articles in medical journals extolling the illusory virtues of chronic opioid therapy and misrepresenting the related risks.<sup>34</sup>

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<sup>30</sup> See, e.g., Margo McCaffery & Chris Pasero, ed. Russell K. Portenoy, “Understanding Your Pain: Taking Oral Opioid Analgesics,” ENDO PHARMACEUTICALS (2004), at 2, available at <https://goo.gl/DnUxRC>; see also, e.g., Endo Pharmaceuticals, “Living With Someone with Chronic Pain” (“Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”).

<sup>31</sup> *Id.* at 3.

<sup>32</sup> *Id.* at 4.

<sup>33</sup> *Id.*

<sup>34</sup> See, e.g., Endo Pharmaceuticals, “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain,” 5 PAIN MEDICINE NEWS 2, at 12-13 (March/April 2007) (describing massive gastrointestinal bleeds resulting from the use of NSAIDs and recommending the use of opioids due to their purported and alleged lack of adverse side effects).

76. ENDO's marketing efforts also included a significant online presence. Upon information and belief, ENDO sponsored, supported, and/or maintained at least two separate websites ([PainKnowledge.com](http://PainKnowledge.com) and [PainAction.com](http://PainAction.com)) which included averments that "[p]eople who take opioids as prescribed usually do not become addicted" and that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them." The websites were operative as of 2009 and 2011, respectively.

77. In addition to these publication-based marketing efforts, ENDO also engaged in direct misleading marketing representations through its sales representatives, including spoken representations and the distribution and publication of promotional and educational materials. Upon information and belief, those representations equally and similarly misrepresented the efficacy of ENDO Opioids, chronic opioid therapy, and the risks related with such treatment options.

78. ENDO also recruited and supported "high" (*i.e.*, frequent) prescribers of ENDO Opioids and other similarly situated physicians to serve as KOLs in order to win influence and prestige for the ENDO Opioids within the medical community. The precise nature and extent of ENDO's Speakers' Bureau and its cultivation of KOLs is unknown to Plaintiff, but is uniquely known to ENDO. Upon information and belief, ENDO approached and retained numerous KOLs in its marketing of the ENDO Opioids and utilized them in the manner described in this Complaint. In 2008 alone, ENDO spent nearly \$4 million to promote approximately 1,000 speaker programs around the country.

79. Prominent examples of ENDO KOLs include Russell Portenoy and Lynn Webster, both of whose work is substantively cited above. To his credit, Dr. Portenoy has since admitted that his actions were responsible for spreading "misinformation" and that he

“gave innumerable lectures in the late 1980s and 90s about addiction that weren’t true.”<sup>35</sup> Dr. Webster was responsible both for the development of a cursory (and ineffective) diagnostic tool called the “Opioid Risk Tool” (*i.e.*, a five-question, one-minute questionnaire) that was purportedly useful in predicting a person’s risk for developing opioid addiction. Dr. Webster was also responsible for disseminating, at ENDO’s behest, various materials regarding so-called “pseudoaddiction,” a term and “condition” that even Dr. Webster has since admitted “became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept.”<sup>36</sup>

80. Upon information and belief, ENDO’s KOLs adhered to ENDO’s dictated “messaging,” which included the creation, distribution, and presentation of articles, publications, medical materials, diagnostic supplements, and CME materials<sup>37</sup> that misrepresented the nature of ENDO Opioids and chronic opioid therapy.

81. ENDO also utilized, co-opted, appropriated, infiltrated, usurped and/or created so-called professional and patient advocacy Front Groups to amplify the reach of its illicit marketing activities, including the American Pain Foundation (the “APF”), the National Initiative on Pain Control (the “NIPC”), the Federation of State Medical Boards (the “FSMB”), the American Pain Society (the “APS”), the American Academy of Pain Medicine (the “AAPM”), and the American Geriatric Society (the “AGS”). ENDO utilized these third-party professional organizations in a variety of ways, including, but not limited to, publishing and popularizing so-called “guidelines” for chronic opioid therapy, publishing

<sup>35</sup> Thomas Catan & Evan Perez, “A Pain-Drug Champion Has Second Thoughts,” *THE WALL STREET JOURNAL* (Dec. 17, 2012).

<sup>36</sup> John Fauber & Ellen Gabler, “Networking Fuels Painkiller Boom,” *THE MILWAUKEE WISCONSIN JOURNAL SENTINEL* (Feb. 19, 2012).

<sup>37</sup> *See, e.g.*, ENDO PHARMACEUTICALS, “Pain Management Dilemmas in Primary Care: Use of Opioids,” *JOURNAL OF FAMILY PRACTICE* (2007) (minimizing the risks of opioid addiction and misrepresenting that potential opioid patients at risk for addiction could be effectively prescreened). In particular, this CME material emphasized the use of erroneous and ENDO-created diagnostic “tools” like the Opioid Risk Tool.

and popularizing articles, educational materials, and promotional materials that were supportive of ENDO Opioids and/or chronic opioid therapy, and supporting and publicizing the work and viewpoints of ENDO KOLs

82. ENDO worked closely with the APF (and its subsidiary the NIPC), providing substantial support to both organizations, exercising editorial control over their content, and taking a substantial role in the variety of misleading and deceptive messages, promotional materials, marketing, and educational products promulgated by APF and/or NIPC at the behest of ENDO. These initiatives included, but are not limited to: (i) creation of misleading CME materials, such as “Persistent Pain in the Older Patient” and “Persistent Pain in the Older Adult,” which misstated that elderly patients presented a decreased risk of addiction compared to younger patients; (ii) materially supporting, collaborating on the creation of and reviewing the materials posted on the NIPC website PainKnowledge.com, which misrepresented that chronic opioid therapy had the potential to improve patients’ ability to function and quality of life; and (ii) the publication of “Exit Wounds,” a highly deceptive and misrepresentative publication aimed at veterans that stated that use of opioids increases functionality and minimized the risks of addiction.

83. In concert with ENDO, the FSMB created “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain” in 1998 and 2004. The Guidelines were thereafter used in 2007 to create a book titled “Responsible Opioid Prescribing,” which was also produced in conjunction with ENDO. Overall, these publications represented (and continue to represent) the use of opioids in the treatment of chronic pain as “essential.” The

publications, and in particular the 2007 book, were widely distributed by the FSMB to state medical boards and practicing doctors.<sup>38</sup>

84. With substantial support and the assistance of ENDO KOLs, the APS and the AAPM issued consensus guidelines in both 1997 and 2009 endorsing the use of opioids in the treatment of chronic pain and minimizing the resulting risks of addiction. The 2009 guidelines were widely publicized, and continue to be cited and republished.

85. In concert with ENDO, the AGS created and disseminated guidelines for the use of opioids for treating chronic pain in 2002 (“The Management of Persistent Pain in Older Persons”) and 2009 (“Pharmacological Management of Persistent Pain in Older Persons”). In particular, the 2009 Guidelines advised, without citation to any authoritative source, that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The 2009 Guidelines also advised that the risks of addiction resulting from chronic opioid therapy “are exceedingly low in older patients with no current or past history of substance abuse.”<sup>39</sup>

86. Reviewing the conclusions of these Front Groups, such as those described above, is also illustrative when viewed in stark contrast to similar guidance issued by an *independent* professional medical organization during the same time frame:

“The recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it. . . . [T]herapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health

<sup>38</sup> Although the 2012 revision no longer recommends chronic opioid therapy as a “first-line” treatment, it does continue to promote the concept of “pseudoaddiction” and managing addiction risk via screening.

<sup>39</sup> See, e.g., “Pharmacological Management of Persistent Pain in Older Persons,” 57 J. AM. GERIATRICS SOC’Y 1331, 1339, 1342 (2009).

risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.”<sup>40</sup>

87. By utilizing third-parties in order to present its questionable viewpoints and misrepresentative “research,” ENDO also created the false perception that the misrepresentations utilized by ENDO were the result of independent, objective research. Thus, it was far more likely to influence the opinions of patients, prescribers, and payors. To date, no reliable scientific data supports the marketing claims advanced by ENDO regarding opioids, chronic opioid therapy, or ENDO Opioids. In fact, as demonstrated by the discussion above, much scientific research directly refutes ENDO, and some of ENDO’s own KOLs and Front Groups have since abandoned their previous positions.

88. The sequence of events surrounding ENDO’s recent application (and subsequent denial) of the approval of an allegedly reformulated version of Opana ER by the FDA is particularly instructive. Specifically, between 2011 and 2012 ENDO rolled out a reformulated version of Opana ER that was, according to ENDO “resistant to crushing” and possessed “properties that make it difficult to manipulate [it] into a soluble form that could be easily drawn into a syringe and subsequently injected by potential abusers.” Overall, this reformulation was intended to address concerns regarding the potential for abuse under the original formulation of Opana ER.

89. On November 30, 2012, ENDO submitted a citizen petition to the FDA in a bid to forestall the release of a generic version of Opana ER (and cancel all other similarly approved generics) under the rationale that the reformulated version was abuse-deterrent.

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<sup>40</sup> See, e.g., Laxmiah Manchikanti, *et al.*, “Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain,” American Society of Interventional Pain Physicians, available at <https://goo.gl/f85L9w>; see also, e.g., U.S. DEPT OF VETERANS AFFAIRS & U.S. DEPT OF DEFENSE, “Clinical Guidelines on Management of Opioid Therapy for Chronic Pain,” (May 2010) available at <https://goo.gl/Wxg6B5> (confirming the “lack of solid evidence based research on the efficacy of long-term opioid therapy”).

90. On May 10, 2013, the FDA denied ENDO's petition, concluding that reformulated Opana ER carried neither additional safety advantages nor sufficiently abuse-deterrent properties that necessitated or justified the relief requested (*i.e.*, the inclusion of FDA-approved labeling stating that Opana ER was effectively abuse-deterrent).

91. Between May 2013 and June 2017, the regulatory position of Opana ER concerning its potential for abuse and contribution to the opioid crisis continued to deteriorate, markedly. On June 8, 2017, the FDA issued a press release that requested ENDO to remove Opana ER, voluntarily, or face formal removal proceedings:

Today, the U.S. Food and Drug Administration requested that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market. After careful consideration, the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse.

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The FDA's decision is based on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation. Injection abuse of reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy). . . .

Opana ER was first approved in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. In 2012, Endo replaced the original formulation of Opana ER with a new formulation intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting. While the product met the regulatory standards for approval, the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER. Now, with more information about the risks of the reformulated product, the agency is taking steps to remove the reformulated Opana ER from the market.

\* \* \*

The FDA has requested that the company voluntarily remove reformulated Opana ER from the market. Should the company choose not to remove the product, the agency intends to take steps to formally require its removal by withdrawing approval. In the interim, the FDA is making health care professionals and others aware of the particularly serious risks associated with the abuse of this product.<sup>41</sup>

92. Despite this first of its kind regulatory action by the FDA in seeking the immediate and outright removal of Opana ER, the unabridged discussion above demonstrates that this is merely the latest in a decades-long course of conduct propagated by ENDO to the detriment of Plaintiff.

93. The same day that the FDA issued this request for the voluntarily withdrawal of Opana ER from the pharmaceuticals market, ENDO issued a defiant press release stating that “[T]his request does not indicate uncertainty with the product’s safety or efficacy when taken as prescribed.”<sup>42</sup> ENDO took no decisive action and, upon information and belief, continued the marketing and sale of Opana ER despite the FDA’s request for withdrawal.

94. On July 6, 2017—and following extensive negotiations with the FDA and a near-month of public pressure—ENDO was forced to concede that despite ENDO’s apparent continued belief “in the safety, efficacy, and favorable benefit-risk profile” of Opana ER, it would finally discontinue the product (but only after netting at least \$194.6 million in profit from their sales of Opana ER up to that point, while the discontinuance of ultimately cost ENDO only \$20 million in pre-tax charges).<sup>43</sup>

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<sup>41</sup> U.S. FOOD & DRUG ADMIN., “FDA requests removal of Opana ER for risks related to abuse,” (June 8, 2017), *available at* <https://goo.gl/M3CE9z>.

<sup>42</sup> “Endo Response to June 8, 2017 FDA Meeting Related to OPANA® ER,” ENDO PHARMACEUTICALS, (June 8, 2017), *available at* <https://goo.gl/7GJ2wF>.

<sup>43</sup> “Endo Provides Update On OPANA® ER,” ENDO PHARMACEUTICALS, (July 6, 2017), *available at* <https://goo.gl/7rTqFV>.



ii. **PURDUE:**

95. PURDUE's misleading course of conduct was pervasive and focused primarily on the promotion of OxyContin (upon information and belief, PURDUE's marketing efforts extended to and included *all* of the PURDUE Opioids identified above).

96. PURDUE's support, synthesis, and proliferation of deeply misleading, purportedly medical and/or scientific materials included advertisements in scholarly journals. As a mere example, PURDUE ran an OxyContin advertisement in a 2005 issue of the *Journal of Pain* that promoted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a dramatization of a man and young boy fishing, with the epithet: "There Can Be Life With Relief." This depiction falsely implied that OxyContin is effective at both long-term pain relief and functional improvement of overall health—claims that are wholly unsubstantiated.

97. PURDUE also regularly advertised in both the *Journal of Pain* and the *Clinical Journal of Pain*, touting false claims suggesting that OxyContin was convenient for both patients and doctors because the drugs were effective for twelve (12) hours at a time (*i.e.*, Q12H). In reality, an allegedly Q12H dose of OxyContin does **not** provide the complete twelve (12) hours of relief that PURDUE claimed, but instead required consistently higher and more frequent dosages to achieve the same level of pain relief in the long-term (*i.e.*, in the treatment of so-called "chronic" conditions). Upon information and belief, Plaintiff asserts that Q12H OxyContin was much more rapidly absorbed (*i.e.*, depleted) than advertised by PURDUE, which was meant to increase the necessary doses required to provide adequate pain relief.

98. PURDUE also published books<sup>44</sup> and pervasively distributed pamphlets that misrepresented the efficacy of and risks associated with PURDUE Opioids and chronic opioid therapy. For example, PURDUE nationally published and distributed a nominally medical and/or scientific pamphlet geared towards law enforcement and prescribers titled “Providing Relief, Preventing Abuse,” which both impermissibly focused on the allegedly isolated incidents of OxyContin being abused via injection, while ignoring other common signs of addictive behavior (*i.e.*, asking for early refills or increased dosages). Moreover, this pamphlet emphasized the scientifically bereft term “pseudoaddiction” to explain potential drug-seeking behavior (and omitting that the concept of “pseudoaddiction” has been roundly rejected by the medical and scientific communities). PURDUE’s nefarious invocation of the term “pseudoaddiction” suggests that addictive behavior can be solved by “completely” treating a patient’s underlying chronic pain (*i.e.*, prescribing more opioids).

99. As a further example, PURDUE disseminated a mailer titled “Pain Vignettes” in 2012 that contained purported individual testimonies of OxyContin patients whose overall functionality and quality of life had been improved by a regular prescription of OxyContin. These claims fly in the face of the well-established medical consensus that long-term use of opioids does not improve life quality or overall functionality.

100. PURDUE’s marketing efforts also encompassed a significant online presence with PURDUE sponsoring, supporting, and/or maintaining at least two separate websites: In the Face of Pain and Partners Against Pain. These unbranded websites continued to press PURDUE’s major argument that the use of PURDUE Opioids (and OxyContin, in particular) were somehow essential to the effective treatment of chronic pain, and labeled

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<sup>44</sup> See, e.g., Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide*, (2007) (produced by the FSMB with significant support from PURDUE and other opioid manufacturers).

skepticism regarding such uses of opioids as being the result of “inadequate understanding” that leads to “inadequate pain control.”

101. In the Face of Pain openly criticized policies that limited access to opioids as being “at odds with best medical practices” and encouraged patients to be “persistent” in finding doctors willing to treat their pain (*i.e.*, prescribed opioids). In the Face of Pain was a gateway for deceptive clinical trials, medical information, and deceptive testimony from seemingly neutral “Advocates” who were actually heavily compensated KOLs and/or patients procured and directed by PURDUE.<sup>45</sup>

102. Similarly, PURDUE utilized its website Partners Against Pain to digitally distribute its 2005 pamphlet titled “Clinical Issues in Opioid Prescribing,” which claimed that “illicit drug use and deception” did not indicate an underlying addiction, but merely meant that the patient’s pain was undertreated: “Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.” In other words, prescribers confronted with potentially addictive behavior from patients should prescribe more opioids, and turning addiction into nothing more than an excuse to sell ever-increasing amounts of PURDUE Opioids.

103. At a higher level, PURDUE also sought to distort the state of medical literature regarding chronic opioid therapy by training its sales representatives to cite, amongst other things, a widely discredited letter-to-the-editor<sup>46</sup> discussing anecdotal observations regarding “narcotics” and addiction. PURDUE’s support and proliferation of

<sup>45</sup> See, e.g., Purdue Pharmaceuticals, “In the Face of Pain® Offers New Tools and Resources to Patients, Caregivers and Healthcare Professionals Advocating for Better Pain Care,” (September 22, 2011), *available at* <https://goo.gl/vZGd6v>.

<sup>46</sup> See, e.g., Jane Porter & Hershel Jick, “Addiction Rare in Patients Treated with Narcotics,” 302(2) NEW ENG. J. MED. 123 (January 10, 1980) (“We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.”).

this misconception was manifested by its sales representatives and publications relying upon this source for unsupported and erroneous claims that the risk of addiction among patients being treated with PURDUE Opioids was greatly diminished.<sup>47</sup>

104. Along similar lines, PURDUE caused a separate study that they had sponsored which ultimately concluded that OxyContin had addiction rates between 8 and 13 percent to be buried in headache-specific literature, so as to minimize its impact.<sup>48</sup>

105. In addition to these indirect marketing efforts, PURDUE also engaged in direct misleading marketing representations through its sales representatives,<sup>49</sup> including spoken representations, the distribution and publication of promotional and educational materials, and telephone solicitations. Upon information and belief, PURDUE continued to contact doctors/prescribers in support of PURDUE Opioids even after those same individuals/entities were placed on “do not call” lists.

106. Upon information and belief, PURDUE employed some 250 sales representatives in 2007 alone, of whom a full 150 were entirely devoted to promoting OxyContin. In 2014, alone, PURDUE spent \$108 million on such direct sales efforts. Upon information and belief, Plaintiff avers that those direct sales materials, representations, and solicitations also misrepresented the efficacy of PURDUE Opioids and the risks

<sup>47</sup> See, e.g., Art Van Zee, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,” 99(2) AM. J. PUB. HEALTH 221 (2014), available at <https://goo.gl/JqWcGA>; see also, e.g., C. Peter N. Watson, *et al.*, “Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy,” 105 PAIN 71 (2003) (citing the Porter & Jicks letter to support the notion that OxyContin is not typically addictive).

<sup>48</sup> See, e.g., Lawrence Robbins, “Long-Acting Opioids for Severe Chronic Daily Headache,” 10(2) HEADACHE QUARTERLY 135 (1999); see also, e.g., Lawrence Robbins, “Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache,” 19 HEADACHE QUARTERLY 305 (1999).

<sup>49</sup> PURDUE targeted individual prescribers and tracked their prescribing habits. These efforts included a secret monitoring program that, over the course of nine years, identified some 1,800 doctors whose prescribing habits demonstrated a high probability that they were writing prescriptions of PURDUE Opioids for addicts and drug dealers. A separate lawsuit filed in the Superior Court of the State of Washington for Snohomish County details that PURDUE was readily able to identify doctors that were operating so-called “pill mills,” and took no action to shut down their proverbial “gold mines.” See, e.g., Complaint, *City of Everett v. Purdue Pharma, L.P., et al.*, Case No. 17-2-00469-31, at ¶¶ 46-61 (January 19, 2017).

associated with chronic opioid therapy. Overall, these marketing efforts ultimately had a substantial and pervasive impact on the regularity with which doctors prescribed OxyContin and the other PURDUE Opioids to their patients.<sup>50</sup> Moreover, PURDUE has been ramping up its promotional efforts in recent years—between 2007 and 2014, PURDUE’s quarterly promotional spending increased from under \$5 million to more than \$30 million.

107. PURDUE also recruited, trained, supported, paid, and utilized high prescribers of PURDUE Opioids and other similarly situated physicians to serve as KOLs in order to win influence and prestige for the PURDUE Opioids within the medical community. Upon information and belief, these KOLs adhered to PURDUE’s dictated “messaging.” PURDUE’s efforts also included the creation, distribution, and presentation of medical supplements and CME materials that misrepresented the nature of Purdue Opioids and chronic opioid therapy, and similar initiatives.

108. The precise nature and complete extent of PURDUE’s cultivation of medical KOLs is unknown to Plaintiff, but is uniquely known to PURDUE. Upon information and belief, PURDUE approached and retained numerous KOLs in its marketing of the PURDUE Opioids and utilized them in the manner described in this Class Action Complaint. Prominent examples of these KOLs include Dr. David Haddox, Dr. Russell Portenoy, and Dr. Lynn Webster. In particular, Dr. Haddox began as a paid PURDUE speaker and ultimately became PURDUE’s Vice President of Risk Management—he was responsible for coining the misleading phrase “pseudoaddiction,” although it was ultimately popularized by Drs. Portenoy and Webster, along with others.

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<sup>50</sup> See, e.g., Art Van Zee, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,” 99(2) AM. J. PUB. HEALTH 221 (2014) (identifying a correlation between the increase in OxyContin prescriptions from 670,000 in 1997 to 6.2 million in 2002 and PURDUE’s doubling of its sales force and trebling of its annual sales calls), available at <https://goo.gl/gp3qQh>.

109. Much of the efforts of PURDUE's KOLs were aimed at influencing prescribing doctors via seminars and CME presentations that were sponsored, underwritten, or otherwise supported by PURDUE, including: (i) a 2011 webinar taught by Dr. Lynn Webster titled "Managing Patient's Opioid Use: Balancing the Need and Risk," which relied heavily on concepts like pseudoaddiction and instructed doctors that "screening tools" like the Opioid Risk Tool and written treatment agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths;" (ii) a February 2012 CME program titled "Safe Opioid Prescribing," which continued to cite the aforementioned 1980 letter-to-the-editor and also falsely emphasized the "competing public health crisis of undertreated pain and prescription drug use;" (iii) a October 2012, PURDUE-sponsored CME titled "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which recommended that the use of "screening tools," more frequent refills, and switching between different opioid formulations could treat high-risk patients who are showing signs of potentially addictive behavior; (iv) a CME titled "Path of the Patient: Managing Chronic Pain in Younger Adults at Risk for Abuse," which suggested that younger chronic opioid therapy patients who are at-risk for addiction may simply be suffering from pseudoaddiction; and (v) a series of CMEs titled "Overview of Management Options," which were issued by the American Medical Association and suggested that opioid alternatives (*i.e.*, NSAIDs) are dangerous at high doses, but which omitted opioids from similar analysis (and despite definitive medical evidence establishing the well-documented risks of treatment via opioids).

110. Defendants have also utilized, co-opted, appropriated, infiltrated, usurped and/or created so-called Front Groups to amplify the reach of its illicit marketing activities, including APF, FSMB, APS, AAPM, and AGS.

111. PURDUE exercised tremendous and constant control over the efforts and conduct of the APF, which were explicitly intended and directed to complement and support PURDUE's own marketing efforts. Pursuant to a "Master Consulting Services Agreement" executed on September 14, 2011, PURDUE was granted contractual editorial and administrative oversight over APF's promotional efforts as well as the unilateral right to terminate the agreement at their discretion.

112. Upon information and belief, PURDUE utilized APF to support its misrepresentative and fraudulent marketing efforts in the following ways: (i) hiring an APF consultant to conduct work on the rollout of the Partners Against Pain website; (ii) hiring an APF consultant to conduct work and promotion of one of PURDUE's opioid-related projects, "Understanding & Coping with Lower Back Pain;" (iii) obtaining "patient representatives" to provide testimonials on "Partners Against Pain;" (iv) soliciting and/or requiring APF board members (including Dr. Lynn Webster) and other PURDUE KOLs and patients to appear on In the Face of Pain as "champions passionate about making a difference in the lives of people who live with pain" (while in fact the parties were well-compensated for their appearances); (v) requiring APF to cede control of its highly influential Pain Care Forum ("PCF") to PURDUE's in-house lobbyist Burt Rosen so that the group's efforts could be directed solely for PURDUE's benefit; (vi) utilizing the PCF to undermine any requirements that prescribers attend CMEs addressing best-practices in the area of chronic opioid therapy; and (vii) utilizing the PCF to parrot PURDUE's own misrepresentative marketing campaign, including the following statement: "[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer patients without prior histories of substance abuse using the medication as directed is rare.

Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug.”<sup>51</sup>

113. PURDUE also collaborated extensively with APF in the publication of various supplements, providing substantial support to the organization and exercising editorial control over content, including: (i) “A Policymaker’s Guide to Understanding Pain & Its Management,” which flagrantly misrepresented that scientific and/or medical studies demonstrated that chronic opioid therapy could improve patients’ “daily function, psychological health and overall health-related quality of life” (no such studies exist), mislabeled potential indicators of dangerous addictive behavior as “pseudoaddiction” that are mere “patient behaviors that may occur when pain is undertreated,” falsely claimed that “less than 1 percent of children treated with opioids become addicted,” and misstated the dangers associated with continually increasing dosages of PURDUE Opioids by claiming that such increased dosages are required to overcome tolerance and is “not necessarily indicative of addiction;” (ii) “Treatment Options: A Guide for People Living with Pain,” which impermissibly minimized the risks of chronic opioid therapy, and denigrated alternative treatment options like NSAIDs by falsely claiming that opioids have “no ceiling dose;” and (iii) “Exit Wounds,” a deceptive publication aimed at veterans that falsely states that the use of opioids increases functionality while grossly minimizing the risks of addiction.

114. PURDUE also acted in concert with FSMB in the creation of the “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain” in 1998 and 2004. In 2007, FSMB utilized the Guidelines to create a book titled *Responsible Opioid*

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<sup>51</sup> “Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Before the S. Committee On the Judiciary,” 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF). Strangely, no medical or scientific support exists for these statements. Moreover, APF’s board of directors included PURDUE KOL’s Russell Portenoy and Scott Fishman, as well as two other members who received consulting fees or had close connections with PURDUE (Lisa Weiss & Perry Fine).



*Prescribing*, which was also produced, disseminated, and popularized in conjunction with, and at the behest of, PURDUE. Overall, FSMB's publications represented (and continue to represent) the use of opioids in the treatment of chronic pain as "essential." The publications were widely distributed by the FSMB to state medical boards and practicing doctors. Although the 2012 revision no longer recommends chronic opioid therapy as a "first-line" treatment, it does continue to promote the concept of "pseudoaddiction" and suggests managing addiction risks via erroneous "screening tools."

115. With PURDUE's support, both the APS and the AAPM issued consensus guidelines in 1997 and 2009 endorsing chronic opioid therapy and minimizing the resulting risks of addiction. At the time that both sets of guidelines were issued, substantial portions of the reviewing and authoring members were in the putative service of PURDUE, including but not limited to Dr. David Haddox and Dr. Russell Portenoy. Although they have since been removed, the 2009 guidelines have been widely publicized, cited, and republished.

116. Cooperatively, PURDUE and AGS created and disseminated guidelines for the use of opioids for treating chronic pain in 2009 ("Pharmacological Management of Persistent Pain in Older Persons"). In particular, these guidelines advised, without citation to any authoritative source, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy" and that the risks of addiction resulting from opioid therapy "are exceedingly low in older patients with no current or past history of substance abuse."<sup>52</sup> Shockingly, the same document also suggested that "all patients with moderate to severe

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<sup>52</sup> See, e.g., "Pharmacological Management of Persistent Pain in Older Persons," 57 J. AM. GERIATRICS SOC'Y 1331, 1339, 1342 (2009).

pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy.”<sup>53</sup>

117. PURDUE utilized these third-party professional organizations in a variety of ways, including, but not limited to, publishing and popularizing so-called “guidelines” for the use of opioids for the treatment of chronic pain, publishing and popularizing articles, educational materials, and promotional materials that were supportive of PURDUE Opioids and/or chronic opioid therapy, supporting and publicizing the work and viewpoints of paid PURDUE KOLs, and other material support and marketing aimed at buttressing the illusory legitimacy of PURDUE Opioids and chronic opioid therapy.

118. Despite Defendants duty to truthfully represent the nature and efficacy of its drugs, these misrepresentations were made purely in service of the pursuit of profit. As a mere snapshot of the lucrative nature of Defendants’ activities reveals, PURDUE’s national annual sales of OxyContin in 2006 were approximately \$800 million. Thereafter, and since 2009, PURDUE’s nationwide sales of OxyContin has increased substantially and fluctuated between approximately \$2.5 billion and \$3 billion, every year.

119. Ultimately and as a direct result of these unscrupulous practices, in May 2007 PURDUE was forced to enter into a Consent Judgment with the Pennsylvania Office of Attorney General (as well as 26 other state jurisdictions) to avoid liability under the Commonwealth’s consumer protection law for its marketing of OxyContin, which required it to pay \$19.5 million and agree to a long list of restrictions on future marketing behavior.<sup>54</sup>

120. Although the consent judgment eventually expired in May 2017, the restrictions required that PURUDE do the following in the marketing of OxyContin: (i)

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<sup>53</sup> *Id.*

<sup>54</sup> *See, e.g., “Consent Judgment,” Commonwealth of Pennsylvania, et al. v. Purdue Pharma, Inc., et al.*, 238 M.D. 2007, (Pa. Commw. May 8, 2007).

refrain from “any written or oral claim that is false, misleading or deceptive;” (ii) refrain from marketing or promotion that is “directly or indirectly inconsistent” with the FDA’s instructions regarding usage; (iii) include “fair balance” statements “regarding OxyContin’s potential for abuse, addiction, or physical dependence;” (iv) refrain from “misrepresentations with respect to OxyContin’s potential for abuse, addiction, or physical dependence;” (v) require that all recipients of “any educational grant, research grant, or other similar Remuneration relating to OxyContin” openly and conspicuously disclose their affiliation; (vi) refrain from misrepresenting “the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence;” (vii) refrain from sponsoring educational events promoting off-label uses of OxyContin; (viii) institute an “OxyContin Abuse and Diversion Detection Program” with regard to PURDUE’s employees; (ix) include “educational information related to detecting and prevent abuse and diversion of opioid analgesics” in all non-branded advertisements; and (x) to overall provide “only information that is truthful, balanced, accurately communicated” and which does not “minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin.”<sup>55</sup>

121. Upon information and belief, PURDUE’s conduct continued despite the existence of this Consent Judgment, up to and continuing after the filing of this civil action.

iii. **ABBOTT:**

122. ABBOTT joined forces with Defendant PURDUE in 1996 through a co-promotion agreement. ABBOTT had a significant sales force already working in hospitals around the country and maintained ongoing relationships with doctors and pain treatment teams. Through the co-promotion agreement, ABBOTT devoted 300 sales representatives to OxyContin sales, which matched the sales force established by PURDUE.

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<sup>55</sup> *Id.* at ¶¶ 2-24.

123. ABBOTT actively marketed OxyContin from 1996 through 2002 and then continued to participate with PURDUE through 2006. With ABBOTT'S help, sales of OxyContin went from \$49 million in the first full year on the market to \$1.6 billion in 2002. Over the life of the agreement, Abbott was paid hundreds of millions of dollars.

124. ABBOTT heavily incentivized its sales force to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers. Top performers were given fanciful titles such as "Wizard of OxyContin" and "Supreme Sovereign of Pain Management." The head of pain care sales, Jerry Eichhorn, was known as the "King of Pain" and signed memos as simply "King."

125. In an internal memo, ABBOTT sales staff were instructed that if a doctor was concerned about the euphoria a patient experienced on the shorter-acting painkiller Vicodin, they should tell the physician "OxyContin has fewer such effects." Yet another memo told sales representatives to highlight the "less abuse/addiction potential" of OxyContin which could be taken just twice a day because of the time-release design. Representatives of ABBOTT were trained to only discuss potential abuse issues if a doctor brought it up and to inform them that "street users" were abusing the drug, and not "true pain patients."

126. Upon information and belief, ABBOTT utilized many of the same techniques as PURDUE with direct-to-physician marketing including food, gifts, and influence peddling, techniques that netted ABBOTT a huge portion of the profits from Purdue Opioid sales. Overall, the sales forces of PURDUE and ABBOTT worked in tandem, holding regular joint strategy sessions, alternating meeting locations between ABBOTT's headquarters and PURDUE's headquarters.

iv. **JOHNSON & JOHNSON:**

127. Similar to the efforts described above, JOHNSON & JOHNSON engaged in deceptive marketing efforts that impermissibly minimized the risks of addiction, overdose, dependence, and death, while simultaneously (and egregiously) overstating the benefits of chronic opioid therapy. Upon information and belief, JOHNSON & JOHNSON spent more than \$90 million on such efforts in 2011, alone.

128. As part of these marketing efforts, JOHNSON & JOHNSON maintained (and currently maintains) the website Prescribe Responsibly, which purports to provide information from “outside experts” provided “for the information of healthcare professionals in the United States only.”<sup>56</sup>

129. In a section titled “Use of Opioid Analgesics in Pain Management,” this website offers numerous statements that fly in the face of established medical science, including: (i) opioids have been utilized to treat chronic pain “for thousands of years;” (ii) opioids “have no true ‘ceiling dose’ for analgesia and do not cause direct organ damage;” (iii) failing to list “death” as a potential side effect of the use of opioid analgesics; (iv) dismissing concerns expressed by practitioners by stating that opioids “are often the only suite agent to control significant” chronic pain; (v) warning that the most severe potential adverse reaction is “the inadequate treatment of pain;” (vi) dismissing concerns about “excessive use of opioid analgesics” leading to a state of hyperalgesia by claiming that “lack of sufficient pain control may itself promote a state of hyperalgesia in the form of persistent pain;” (vii) dismissing concerns about the potential for addiction resulting from the use of opioids as “overestimated” and claiming that “true addiction occurs only in a small percentage of

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<sup>56</sup> JOHNSON & JOHNSON, “Prescribe Responsibly,” (July 2, 2015), *available at* <https://goo.gl/cGHgWG> (last accessed February 28, 2018).

patients with chronic pain who receive chronic opioid analgesics”; and (viii) concluding that “no agents have fully replaced opioid analgesics for the treatment of moderate to severe pain.”<sup>57</sup> These averments flagrantly misrepresent that opioids are considered standard in the treatment of so-called “chronic pain,” drastically understates the underlying risks of utilizing opioids (even in the short-term), while encouraging physicians to prescribe opioids freely and aggressively. Overall, JOHNSON & JOHNSON are utilizing the legitimate pain of its customers as a form of improper commercial coercion.

130. JOHNSON & JOHNSON also utilizes this website to advocate dangerously misinformative concepts such as “pseudoaddiction”<sup>58</sup> and “pseudotolerance”<sup>59</sup> that are intended to misrepresent and minimize the serious risks posed by the use of opioids. PrescribeResponsibly also draws an unsupported and outrageous distinction between addiction and physical dependence:

Physical dependence with long-term use of opioids should be expected. It is important to note that physical dependence is not the same as addiction. Physical dependence is a state of physiological adaptation manifested by a withdrawal syndrome produced by abrupt discontinuation of a medication . . . . Addiction is characterized by continued use of a drug despite detrimental effects and self-harm, impaired control over the use of a drug.

This distinction egregiously invites treating physicians to ignore the emergent signs of addiction as a mere hallmark of utilizing opioids in the long-term, as opposed to indications of a serious addiction-related condition.

<sup>57</sup> See, e.g., JOHNSON & JOHNSON, “Use of Opioid Analgesics in Pain Management,” (July 2, 2015), *available at* <https://goo.gl/ZTA9bR> (last accessed on February 28, 2018).

<sup>58</sup> See, e.g., JOHNSON & JOHNSON, “Before Prescribing Opioids,” (July 2, 2015), *available at* <https://goo.gl/EqkRvY> (last accessed on February 28, 2018) (“Pseudoaddiction is a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.”).

<sup>59</sup> *Id.* (“Pseudotolerance is the need to increase medication such as opioids for pain when other factor(s) are present such as disease progression, new disease, increased physical activity, lack of compliance, change in medication, drug interaction, addiction, and/or deviant behavior.”).

131. Similar representations appear in a section titled “Before Prescribing Opioids,” which advances circular and deeply misrepresentative theories concerning addiction and tolerance to opioids, arguing that “[c]onfusion between physical dependence and addiction may contribute to the undertreatment of chronic pain.” These representations include: (i) “[p]hysical dependence is a natural, expected neuroadaptive response that can occur with opioids;” (ii) “[t]olerance is also a natural, expected physiologic response” which is “neither good nor bad;” (iii) claiming that “[o]ne can treat acute pain in the face of an active addiction” with the use of opioids; (iv) arguing that the “stress” resulting from inadequately treated chronic pain is “[o]ne of the most common reasons for relapse of patients with addiction;” and (v) generally espousing that addiction concerns in the context of using opioids to treat chronic pain is something that can be eliminated through mere administrative measures.

132. The import of these representations is two-fold: (i) it seeks to draw non-existent distinctions between the addiction-related behaviors discussed above so as to assuage physician’s fears (and, thereby, encourage the same physicians to prescribe ever-increasing amounts of opioids to their patients); and (ii) suggest that addiction-related behaviors are simply the result of undertreated chronic pain (and, thereby, encourage the same physicians to prescribe ever-increasing amounts of opioids to their patients). JOHNSON & JOHNSON undertook these misrepresentations, despite knowledge of the very serious dangers related to addiction posed by chronic opioid therapy.

133. Upon information and belief, JOHNSON & JOHNSON also engaged in direct misleading marketing representations through its sales representatives, including spoken representations, the distribution and publication of promotional and educational materials, and telephone solicitations. Upon information and belief, JOHNSON &

JOHNSON instructed its sale representatives (directly and through training/administrative materials) to do the following: (ii) to trivialize and minimize the risks of addiction and withdrawal symptoms posed by the use of J&J Opioids; (iii) to claim that J&J Opioids had an exceedingly low incidence of withdrawal symptoms and that most patients who ceased utilizing J&J Opioids; (iv) to overemphasize the risks posed by pharmaceutical competitors with opioids (*e.g.*, NSAIDs); and (v) to claim that J&J Opioids can improve patients' quality of life and functionality. JOHNSON & JOHNSON instructed its sales representatives as above despite direct knowledge regarding the prolific problems regarding addiction, the dangers and risks posed by chronic opioid therapy, and the lack of a proper foundation in medical science.

134. Upon information and belief, JOHNSON & JOHNSON also maintained (and currently maintains) a Speakers Bureau and cultivated KOLs to help spread its deceptive message. The exact extent of these activities is presently unknown to Plaintiff, but is uniquely known to JOHNSON & JOHNSON.

135. Lastly, JOHNSON & JOHNSON also cooperated with various Front Groups in the creation and dissemination of additional misleading materials and information regarding J&J Opioids and chronic opioid therapy, in general. These activities included, but were not limited to: (i) collaborating with and exercising control over the AAPM and the AGS to create and disseminate a pamphlet titled "Finding Relief: Pain Management for Older Adults;"<sup>60</sup> (ii) collaborating with and exercising control over AGS in the production

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<sup>60</sup> In relevant part, this pamphlet makes a number of erroneous and troubling claims regarding chronic opioid therapy, including the following: (i) "opioids are rarely addictive when used properly for the management of chronic pain;" (ii) "opioids may make it easier for people to live normally;" (iii) rejecting the notion that "[o]pioid doses have to get bigger over time because the body gets used to them" by claiming that "you will probably remain on the same dose or need only small increases over time;" (iv) failing to advise of the serious risks posed by chronic opioid therapy, and representing those risks as merely "upset stomach or sleepiness;" and (v) claiming that "opioid medications make it possible for people with chronic pain to 'return to normal.'"



and dissemination of an aforementioned set of guidelines titled “Pharmacological Management of Persistent Pain in Older Persons;” (iii) collaborating and exercising control over APF, AAPM, and the American Society of Pain Management Nursing (“ASPMN”) in the creation and maintenance of a website titled Let’s Talk Pain that explicitly promoted the use of J&J Opioids and chronic opioid therapy;<sup>61</sup> and (iv) collaborating and exercising control over the APF in the publication of “Exit Wounds,” a publication that extolled the alleged virtues of chronic opioid therapy to veterans.<sup>62</sup>

136. Upon information and belief, JOHNSON & JOHNSON also sought to influence physicians through the creation and support of CMEs designed to misrepresent the efficacy of J&J Opioids and chronic opioid therapy and to play down the associated risks of such therapeutic treatments.

v. ALLERGAN:

137. ALLERGAN also engaged in deceptive marketing efforts that impermissibly minimized the medical risks of using opioids (even normally and as prescribed) and the risks of addiction, overdose, dependence, and death, while simultaneously (and egregiously) overstating the benefits of chronic opioid therapy. Upon information and belief, ALLERGAN spent some \$6.7 million on such promotional efforts in 2011, alone.

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*See, e.g., AAPM, et al., “Finding Relief: Pain Management for Older Adults” (2009), at 17. All of these claims are demonstrably false, and fly in the face of medical science and evidence-based medicine. Overall, this pamphlet also portrays opioids as a “cure-all” that is simultaneously the most-effective and least-dangerous option for the treatment of chronic pain (even though the opposite is true in both respects).*

<sup>61</sup> Similarly, while it was still live, was intended to emphasize the illusory efficacy of chronic opioid therapy, and attempt to market J&J Opioids. The content on this website also minimized the risks of addiction (“Understanding Addiction”) by claiming that signs of “physical dependence” are not indications of addiction-related behavior and utilizing terms like “pseudoaddiction” to play down the seriousness of these concerns (and, thereby, encourage the wider use of J&J Opioids and chronic opioid therapy).

<sup>62</sup> Upon information and belief, Plaintiff avers that this pamphlet explicitly extols and inflates the potential benefits of chronic opioid therapy. In concert with JOHNSON & JOHNSON, APF cause this pamphlet to be distributed to organizations that support veterans recovering from battlefield injuries sustained in military service to the United States of America.

138. Upon information and belief, ALLERGAN's marketing efforts took many forms, including: (i) promotional materials intended to exaggerate and misrepresent the efficacy of Kadian and chronic opioid therapy to neuropathic pain patients and geriatric patients (*i.e.*, the elderly); (ii) instituted direct marketing practices that targeted and tracked Kadian and chronic opioid therapy prescribing habits of physicians; (iii) trained its sales representatives to advance numerous erroneous and dangerously incorrect averments to prescribing physicians regarding Kadian and chronic therapy, including unproved claims that Kadian improved function/quality of life, had diminished risks of addiction/withdrawal symptoms, and false scientific concepts like "pseudoaddiction" and the lack of a "ceiling dose" when prescribing opioids for pain management; (iv) misrepresenting the efficacy of so-called "screening tools" to identify potential risks associated with opioid use; (v) claiming without proof that Kadian provides more consistent pain relief than other opioids; and (vi) overstated or exaggerated the potential risks associated with opioid alternatives like NSAIDs.

139. Upon information and belief, ALLERGAN maintained a Speakers Bureau and cultivated KOLs to spread substantially identical or similar disinformation regarding Kadian and chronic opioid therapy. ALLERGAN's Speakers Bureau and KOLs received training similar to ALLERGAN's sales representatives regarding the optimal ways to "sell" Kadian and chronic opioid therapy, and were compensated for their troubles. Consistent with these efforts, ALLERGAN also supported various KOLs and prescribing physicians in drafting and publishing articles in both the *Journal of Pain* and the *Journal of the American Geriatrics Society* extolling the potential virtues of Kadian and chronic opioid therapy.

140. Upon information and belief, ALLERGAN also collaborated and/or exercised control over various Front Groups in their pursuit of the above marketing initiatives, including but not limited to the AAPM and the APS.

141. Upon information and belief, ALLERGAN also sought to influence physicians through the creation and support of CMEs designed to misrepresent the efficacy of Kadian and chronic opioid therapy and to portray a diminished assessment of the associated risks of such therapeutic treatments.

142. The extent of ALLERGAN's misrepresentations regarding Kadian, in particular, eventually aroused the suspicion and scrutiny of the FDA Division of Drug Marketing, Advertising and Communications ("DDMAC"), which concluded that various brochures submitted ALLERGAN were "false and misleading because they omit and minimize the serious risks associated with [Kadian], broaden and fail to present the limitations to the approved indication of [Kadian], and present unsubstantiated superiority and effectiveness claims." In a letter dated February 18, 2010, the FDA ultimately concluded that ALLERGAN's marketing efforts "are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."

143. This communication clearly delineates ALLERGAN's folly:

[T]he promotional materials fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed, interactions with alcohol and drugs of abuse, impaired respiration, head injury and increased intracranial pressure, hypotensive effect, interactions with other central nervous system depressants, gastrointestinal obstruction, and anaphylaxis. Similarly, the promotional materials fail to reveal precautions related to use in patients with prior analgesic treatment experience; use in certain patient populations with narrow therapeutic index for opioid analgesics; use in patients with acute abdominal conditions; use in patients with convulsive disorders; use in patients undergoing cordotomy; use in pancreatic/biliary tract disease; tolerance and physical dependence with use of opioids; use in special risk groups; and risk associated with driving and operating machinery.

\* \* \*

The overall effect of these presentations minimizes the risks associated with Kadian and misleadingly suggests that Kadian is safer than has been demonstrated.

\* \* \*

Although Kadian may help treat patients' moderate to severe pain, we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience (such as the common adverse events of drowsiness, dizziness, constipation and nausea), results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life. In addition, we are not aware of any studies demonstrating that the level of pain reduction experience by patients on Kadian therapy corresponds with a positive impact on the outcomes claimed.

\* \* \*

[The Division of Drug Marketing, Advertising, and Communications] requests that [ALLERGAN] immediately cease the dissemination of violative promotional materials for Kadian such as those described above.<sup>63</sup>

**vi. ALLEGATIONS AS TO REMAINING DEFENDANTS:**

144. Upon information and belief, the remaining DEFENDANTS (*e.g.*, MALLINCKRODT, ABBVIE, ZOGENIX, PERNIX, WEST-WARD, SHIONOGI, and VALIDUS) have all acted similarly and in conformance with the course of conducts described above at length in promoting and distributing their respective products.<sup>64</sup>

**vii. ALLEGATIONS AS TO ALL DEFENDANTS:**

145. At all times relevant hereto, DEFENDANTS also took steps to avoid detection of and to fraudulently conceal their deceptive marketing and conspiratorial behavior. DEFENDANTS disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through various third parties, KOLs, and Front

<sup>63</sup> U.S. FOOD & DRUG ADMIN., "Letter RE: NDA #20-616 Kadian® (morphine extended-release) Capsules, CII MACMIS #18148)," (February 18, 2010).

<sup>64</sup> See, *e.g.*, *supra* at ¶ 68.

Groups. DEFENDANTS purposefully hid behind these individuals and entities to avoid regulatory scrutiny and to prevent doctors and the public from discounting its messages.

146. In addition to hiding their own roles in generating the deceptive content, DEFENDANTS manipulated their promotional materials and the scientific literature to make it appear that the DEFENDANTS' deceptive message was accurate, truthful, and supported by substantial scientific evidence. DEFENDANTS distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The true lack of support for DEFENDANTS' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by Plaintiff.

147. While the opioid epidemic was raging, DEFENDANTS intentionally concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that Plaintiff now asserts. Plaintiff was not alerted to the existence and scope of DEFENDANTS' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through its public statements, marketing, and advertising, DEFENDANTS' deceptions deprived Plaintiff of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

148. As a consequence of DEFENDANTS' collusion and deceptive marketing, the number of opioid-related overdoses and opioid-related addiction/dependence cases requiring medical intervention amongst the FUND's covered individuals has increased exponentially. In particular, treatment of these recognized, direct, and quantifiable medical results of DEFENDANTS' illegal behavior has required the prolific prescription and use of

medications containing the drug naloxone (*e.g.*, Suboxone, Narcan, *etc.*) which reverses the effects of opioids and can save individuals from otherwise-fatal overdoses of opioids.

149. At all times relevant hereto, Plaintiff hereby avers that DEFENDANTS' conduct described above (as well as the conduct of DEFENDANTS' employees, agents, KOLs, Front Groups, and any other co-conspirators) was directed at and/or targeted the FUND and its beneficiaries, as well as at doctors/prescribers, healthcare facilities, patients, and commercial markets located in the Commonwealth of Pennsylvania, generally, and Philadelphia City and County, specifically.

150. Upon information and belief, Plaintiff avers that DEFENDANTS' course of conduct described above stretches across decades and continues up to the date of the filing of this Complaint.

## **COUNT I**

### **INSURANCE FRAUD (CIVIL)**

151. Plaintiff incorporates herein by reference all other paragraphs of this Complaint as if fully set forth herein at length.

152. Plaintiff's claim against DEFENDANTS for insurance fraud is brought pursuant to 18 Pa.C.S. § 4117(g), which provides a civil cause of action to insurers that are damaged as a result of conduct declared illegal under 18 Pa.C.S. §§ 4117(a)-(b).

153. Plaintiff is an "insurer" as defined by Section 4117(l). *See, e.g.*, 18 Pa.C.S. § 4117(l) (including, but not limited to, "an unincorporated association of underwriting members," "a fraternal benefits society," and/or "a self-insured health care entity").

154. DEFENDANTS are each considered a "person" under the meaning of Section 4117(a). *See, e.g.*, 18 Pa.C.S. § 4117(a).

155. DEFENDANTS' pattern and course of conduct described throughout this Complaint constitute serial violations of Section 4117(a)(2), which criminalizes the behavior of anyone who "[k]nowingly and with the intent to defraud any insurer or self-insured, [present] or [cause] to be presented to any insurer or self-insured any statement forming a part of, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim." 18 Pa.C.S. § 4117(a)(2).

156. DEFENDANTS' pattern and course of conduct described throughout this Complaint also constitute serial violations of Section 4117(a)(3), which criminalizes the behavior of anyone who "[k]nowingly and with the intent to defraud any insurer or self-insured, assists, abets, solicits or conspires with another to prepare or make any statement that is intended to be presented to any insurer or self-insured in connection with, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim, including information which documents or supports an amount claimed in excess of the actual loss sustained by the claimant." 18 Pa.C.S. § 4117(a)(3).

157. DEFENDANTS' pattern and course of conduct described throughout this Complaint also constitute serial violations of Section 4117(a)(5), which criminalizes the behavior of anyone who "[k]nowingly benefits, directly or indirectly, from the proceeds derived from a violation of this section due to the assistance, conspiracy or urging of any person." 18 Pa.C.S. § 4117(a)(5).

158. Specifically, DEFENDANTS and each of them together with their named and unnamed co-conspirator KOLS, associated Front Groups, employees, agents, servants, officers, directors, and other representatives, misrepresented, deceived, concealed, omitted, and/or failed to inform Plaintiff FUND and its participants, retirees, and their dependents,

and the doctors prescribing OPIOIDS that the use of OPIOIDS was neither safe nor efficacious in the treatment of chronic pain or other long-term medical conditions.

159. To the contrary, DEFENDANTS affirmatively did the opposite by convincing Plaintiff and the FUND's participants, retirees, and their dependents and the prescribing doctors that the use and ever regular or continued use was safe and effective for the treatment of chronic pain and other long term medical conditions. DEFENDANTS' impermissible behavior is well-described throughout this Complaint, and includes direct and indirect (*i.e.*, carried out by DEFENDANTS' agents, employees, representatives, paid speakers, servants, and/or KOLs) actions: (a) concealing, deceiving, obfuscating, or otherwise misrepresenting the results of definitive medical studies and persuasive empirical research demonstrating the dangers associated with chronic opioid therapy and OPIOIDS; (b) deliberately misrepresenting and/or deceptively describing the efficacy of OPIOIDS at managing chronic pain and other long-term medical conditions; (c) publishing or causing to be published various materials containing false or deceptive information upon which physicians, Plaintiff and the FUND's participants, retirees, and their dependents relied upon in choosing to prescribe, pay for, or take OPIOIDS when safer, more effective, and less expensive treatments were available for the management of chronic pain and other long-term medical conditions; and (d) otherwise creating confusion and uncertainty regarding the safe, recommended, and medically sound therapeutic uses of OPIOIDS.

160. In so doing, DEFENDANTS deprived the FUND and its participants, retirees, and their dependents, and the prescribing doctors treating those same individuals of information that was relevant, material, and vital to the decision of whether or not to prescribe OPIOIDS to Plaintiff's beneficiaries under their health insurance plans.



161. These serial misrepresentations of material facts regarding the efficacy and safety of OPIOIDS perpetrated by DEFENDANTS ultimately caused (and were intended to cause) the FUND and its participants, retirees, and their dependents to either purchase—or seek reimbursements for the purchase of—OPIOIDS marketed by DEFENDANTS for purposes and/or treatments that were inconsistent with the medically and/or scientifically approved uses of such drugs (*i.e.*, chronic opioid therapy).

162. DEFENDANTS' misrepresentations also caused a dramatic increase in the number of opioid-related overdoses and opioid-related addiction/dependence cases requiring medical intervention amongst the FUND's covered individuals. Plaintiff is also seeking compensation for the treatment of these recognized, direct, and quantifiable medical results of DEFENDANTS' illegal behavior, including, but not limited to, the prolific prescription and use of medications containing naloxone.

163. DEFENDANTS' schemes discussed throughout this Complaint were calculated to ensure that the FUND would be wrongfully induced to cover and/or reimburse for these expenses related to the purchase and use of OPIOIDS, thereby enriching DEFENDANTS at the expense of Plaintiff.

164. DEFENDANTS' were and are aware that Plaintiff depended upon the accuracy and reasonableness of a patients' course of treatment when deciding whether to approve and pay for related expenses, up to and including the cost of OPIOIDS.

165. The above-described pattern of insurance fraud amounted to a common course of conducted intended to deceive Plaintiff. Each fraudulent act was related, had similar purposes, involved similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff. DEFENDANTS' fraudulent activities

were and are part of its regular way of conducting its ongoing business, and constitute a present and continuing threat to Plaintiff.

166. By reason of the foregoing and as a proximate cause of said pattern of fraudulent activity and acts committed in furtherance thereof, Plaintiff has suffered injury and has been damaged as alleged herein.

167. Each of the fraudulent acts detailed in this Complaint constitutes “insurance fraud” within the meaning of 18 Pa.C.S. §§ 4117(a)(2)-(3), (5). Collectively, these violations constitute a pattern of fraudulent behavior within the meaning of 18 Pa.C.S. § 4117(g).

**WHEREFORE**, Plaintiff respectfully requests that this Honorable Court enter judgment against DEFENDANTS on Count I and award Plaintiff actual and statutory damages for each instance of fraudulent behavior that resulted in a claim (*i.e.*, the payment by Plaintiff for each claim presented for each and every one of the OPIOIDS they manufactured; and each instance in which DEFENDANTS misrepresented and/or deceptively represented the efficacy and risks associated with, or otherwise obfuscated the truth regarding the therapeutic uses of OPIOIDS and chronic opioid therapy), consequential damages (*i.e.*, each and every instance when Plaintiff paid for the treatment of an opioid-related overdose or opioid-related addiction treatment, including prescriptions for naloxone-based medications), treble damages, together with interest, costs of investigation, costs of litigation, reasonable attorneys’ fees, and expenses in an amount in excess of \$50,000 and such other relief as the Court deems appropriate.

## **COUNT II**

### **DISGORGEMENT OF PROFITS**

168. Plaintiff incorporates herein by reference all other paragraphs of this Complaint as if fully set forth herein at length.

169. DEFENDANTS are the manufacturer, seller, and/or supplier of OPIOIDS. Through the wrongful and deceptive conduct described at length above, DEFENDANTS have reaped substantial profits from the sale of OPIOIDS. Yet, DEFENDANTS' profits would have been significantly and substantially reduced but for their wrongful, deceptive and unlawful conduct.

170. Accordingly, and as described in this Complaint, DEFENDANTS have been unjustly enriched by their unlawful, deceptive and wrongful conduct. DEFENDANTS should not be allowed to retain the proceeds from the benefits conferred upon them by Plaintiff (*i.e.*, the purchase and/or reimbursement for purchase of OPIOIDS). DEFENDANTS knew that Plaintiff paid for, or reimbursed for purchases of, OPIOIDS that were not medically necessary, generally ineffective, and fundamentally unsafe. Moreover, the use of OPIOIDS in the treatment of chronic pain and/or other long-term medical conditions offered no greater benefits than those offered by less expensive medications and treatment options.

171. It is unjust and inequitable to permit DEFENDANTS to enrich themselves at the expense of Plaintiff by retaining the benefit of the various expenditures for OPIOID prescriptions that were not medically necessary, effective, or, alternatively, no more efficacious than less expensive, substantially safer medical alternatives, or that were simply the result of DEFENDANTS' own deceptive marketing strategies. Accordingly, DEFENDANTS must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution and/or rescission to Plaintiff.

**WHEREFORE**, Plaintiff respectfully requests that this Honorable Court enter judgment in their favor and against DEFENDANTS for compensatory and actual damages related to their purchases and reimbursement for purchases of OPIOIDS, in an amount in

excess of \$50,000, together with interest, costs of litigation, attorneys' fees, and any other such relief as this Honorable Court may deem just and proper.

### **COUNT III**

#### **BREACH OF IMPLIED WARRANTIES**

172. Plaintiff incorporates herein by reference all other paragraphs of this Complaint as if fully set forth herein at length.

173. DEFENDANTS, in the manufacture, marketing, and sale of OPIOIDS impliedly warranted to Plaintiff that OPIOIDS were appropriate for their particular and understood ordinary purpose as presented by DEFENDANTS: namely, the treatment of chronic pain and/or other long-term medical conditions.

174. DEFENDANTS and its agents, employees, servants, paid speakers, KOLs and/or other representatives knew or should have known that OPIOIDS were ineffective (and inherently dangerous) treatment options in the management of chronic pain and other long-term medical conditions.

175. Plaintiff reasonably relied upon the skill and judgment of DEFENDANTS and its agents, employees, servants, paid speakers, KOLs and/or other representatives as to whether OPIOIDS were of merchantable quality, safe, and fit for their intended uses as described by DEFENDANTS.

176. Pursuant to the Pennsylvania Commercial Code,<sup>65</sup> there exists an implied warranty of merchantability for DEFENDANTS marketing and sale of OPIOIDS. *See, e.g.,* 13 Pa.C.S. §§ 2314-15.

177. DEFENDANTS breached this implied warranty of merchantability by promoting, marketing, and selling OPIOIDS as being fit for the "ordinary purpose" ascribed

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<sup>65</sup> 13 Pa.C.S. §§ 1101, *et seq.*

by DEFENDANTS (*i.e.*, the treatment of chronic pain and/or other long-term medical conditions) when, in fact, OPIOIDS are inappropriate, dangerous, and unfit for that purpose.

**WHEREFORE**, Plaintiff respectfully requests that this Honorable Court enter judgment for them and against DEFENDANTS, for compensatory and consequential damages related to their purchases and reimbursements for purchases of OPIOIDS, in an amount in excess of \$50,000, together with interest, costs of litigation, attorneys' fees, and all other such relief as this Honorable Court may deem just and proper.

#### **COUNT IV**

##### **CIVIL CONSPIRACY**

178. Plaintiff incorporates herein by reference all other paragraphs of this Complaint as if fully set forth herein at length.

179. DEFENDANTS conspired amongst themselves and with various KOLs and Front Groups as described throughout this Complaint in order to commit unlawful acts, including the serial violations of the Pennsylvania Insurance Fraud Statute detailed at length above. In particular, DEFENDANTS and the various KOLs and Front Groups knowingly and voluntarily agreed to present or cause to be presented statements used in whole or in part, to support a claim for payment for OPIOIDS that contained false, incomplete and/or misleading information concerning the material facts regarding the uses, need for, and prescribing of OPIOIDS simply to promote the use of OPIOIDS for the treatment of chronic pain and other long-term medical conditions. To that end, DEFENDANTS cooperated amongst themselves, and enlisted various KOLs and Front Groups to produce and disseminate statements and materials in furtherance of this common strategy, despite knowledge of the misleading nature of these activities.

180. Together with and in collusion with Front Groups including the APF, NIPC, AGS, FSMB, APS, and AAPM, DEFENDANTS agreed to deceptively and misleadingly promote the benefits and superiority of chronic opioid therapy and OPIOIDS, while minimizing the associated risks. As part of these agreements, DEFENDANTS provided material, financial, and other forms of support to the Front Groups, which in turn used that support to more broadly disseminate the deceptive and misleading messaging regarding OPIOIDS and chronic opioid therapy. The publications, marketing materials, CMEs, programs, and substantive representations produced and publicized by these Front Groups are each products of a civil conspiracy, and each instance of collaboration between DEFENDANTS and the Front Groups is evidence of an overt act taken in furtherance of that conspiracy.

181. Together and in collusion with KOLs including David Haddox, Lynn R. Webster, Russell Portenoy, Kathleen Foley, Christine A. Miaskowski, Michael J. Brennan, Perry Fine, Scott Fishman, Lisa Weiss, and others unknown to Plaintiff but known to and identifiable to DEFENDANTS, DEFENDANTS agreed both overtly and tacitly among themselves and others, to deceptively and misleadingly promote the benefits and superiority of chronic opioid therapy and OPIOIDS, while minimizing the associated risks. As part of these agreements, DEFENDANTS provided material, financial, and other forms of support to the KOLs, who in turn used that support to more broadly disseminate the deceptive and misleading messaging regarding OPIOIDS and chronic opioid therapy. The publications, marketing materials, CMEs, programs, and substantive representations produced and publicized by these KOLs are each products of a civil conspiracy, and each instance of collaboration between DEFENDANTS and the KOLs is evidence of an overt act taken in furtherance of that conspiracy.

182. DEFENDANTS also mutually worked amongst themselves towards a shared common purpose, and explicitly cooperated with one another in the pursuit of that common purpose. Specifically, that purpose included: (i) the popularization and proliferation of “chronic opioid therapy,” and (ii) the increase of sales of OPIOIDS. DEFENDANTS explicitly cooperated in the sale of certain OPIOIDS, including but not limited to ABBOTT and PURDUE’s cooperation in the sales of OxyContin. Each such instance of collaboration between DEFENDANTS in pursuit of this common purpose is evidence of an overt act taken in furtherance of that conspiracy.

183. DEFENDANTS also explicitly cooperated in their support, control of, and direction of the Front Groups and KOLs discussed above. DEFENDANTS’ material support of the Front Groups and KOLs are products of a civil conspiracy, and each instance of collaboration between DEFENDANTS in supporting the efforts of the Front Groups and KOLs is evidence of an overt act taken in furtherance of that conspiracy.

184. Each of the participants in this conspiracy were fully aware of the deceptive and misleading nature of the statements, research, and other materials that they utilized in promoting OPIOIDS. Nonetheless, DEFENDANTS and the Front Groups agreed to mislead and deceive Plaintiff regarding the risks, benefits, and alleged superiority of chronic opioid therapy and OPIOIDS, in exchange for increased pharmaceutical sales, financial contributions, reputational enhancements, and other pecuniary and professional benefits.

185. As outlined at length above, DEFENDANTS played an active role in determining the substance and format of the misleading and deceptive messaging issued by KOLs and Front Groups, including directly providing content, editing, and otherwise approving content produced by its co-conspirators. DEFENDANTS, KOLs, and Front Groups also collectively ensured that these materials were widely disseminated by

cooperative distribution, material support and republication. The result was an unrelenting stream of misleading information regarding the risks, benefits, and alleged superiority of chronic opioid therapy and OPIOIDS.

186. Even if DEFENDANTS did not directly disseminate or control the content of all of these misleading and deceptive representations, they are liable for conspiring with the third parties that did so (*i.e.*, KOLs and Front Groups).

187. DEFENDANTS' conspiracy, and the consummation of that conspiracy via the overt acts described above, amongst themselves and with these third parties (*e.g.*, KOLs and Front Groups) were unlawful (criminal and civil) acts under the Pennsylvania Insurance Fraud Statute, 18 Pa.C.S. §4117.

188. Upon information and belief, Plaintiff avers that DEFENDANTS' conspiracy, and the actions consummating that conspiracy, were undertaken with malice.

189. As a result of DEFENDANTS' conspiracy and related unlawful acts, Plaintiff has been damaged and continues to be damaged by paying for the costs of or reimbursements for OPIOIDS for the treatment of chronic pain and/or other long-term medical conditions.

190. Because DEFENDANTS' conspiracy ultimately caused doctors and other health care providers to prescribe (and, consequently, Plaintiff to pay for) long-term treatments via OPIOIDS, DEFENDANTS caused and is responsible for those costs and claims. In addition, DEFENDANTS are both criminally and civilly liable for the insurance fraud they perpetrated upon Plaintiff and others arising out of and directly caused by their knowing and intentional conduct described above.

**WHEREFORE**, Plaintiff respectfully requests that this Honorable Court enter judgment for them and against DEFENDANTS, for direct and consequential damages



related to their purchases and reimbursements for purchases of DEFENDANTS' Opioids, in an amount in excess of \$50,000, together with interest, costs of litigation, attorneys' fees, and all other such relief as this Honorable Court may deem just and proper.

ANAPOL WEISS

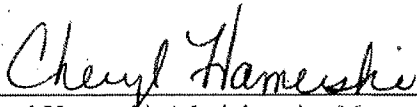
BY: /s/ DAVID S. SENOFF  
SOL H. WEISS, ESQUIRE  
DAVID S. SENOFF, ESQUIRE  
HILLARY B. WEINSTEIN, ESQUIRE  
CLAYTON P. FLAHERTY, ESQUIRE  
130 N. 18<sup>TH</sup> STREET, SUITE 1600  
PHILADELPHIA, PA 19103

*ATTORNEYS FOR PLAINTIFF*

DATED: APRIL 24, 2018

**VERIFICATION**

I, Cheryl Hamerski, do verify that the information contained in the foregoing Complaint is true and correct to the best of my knowledge, information and belief. I understand that false statements herein made are subject to the penalties of 18 Pa.C.S. §4904 relating to unsworn falsification to authorities.

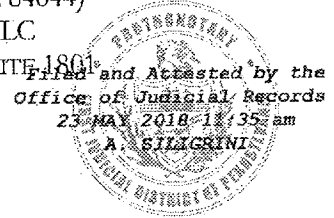
  
Cheryl Hamerski, Administrative Manager  
UFCW, Local 23 and Employers Health Fund

DATED: 4/24/18

## **EXHIBIT B**

SOL H. WEISS, ESQ. (No. 15925)  
 DAVID S. SENOFF, ESQ. (No. 65278)  
 HILLARY B. WEINSTEIN, ESQ. (No. 209533)  
 CLAYTON P. FLAHERTY, ESQ. (No. 319767)  
 ANAPOL WEISS  
 ONE LOGAN SQUARE  
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ATTORNEYS FOR PLAINTIFF

IRON WORKERS DISTRICT COUNCIL OF  
 PHILADELPHIA AND VICINITY, BENEFIT  
 FUND,  
 2 INTERNATIONAL PLAZA DRIVE  
 INTERNATIONAL PLAZA TWO, SUITE 120  
 PHILADELPHIA, PENNSYLVANIA 19113

PLAINTIFF,

v.

ABBOTT LABORATORIES, INC.  
 100 ABBOTT PARK ROAD  
 ABBOTT PARK, IL 60064

AND

ABBVIE, INC.  
 1 N. WAUKEGAN ROAD  
 NORTH CHICAGO, IL 60064

AND

DEPOMED, INC.  
 7999 GATEWAY BLVD., STE. 300  
 NEWARK, CA 94560

AND

ENDO PHARMACEUTICALS, INC.  
 1400 ATWATER DRIVE  
 MALVERN, PA 19355

COURT OF COMMON PLEAS  
 PHILADELPHIA COUNTY

CASE NO.

CIVIL ACTION

JURY TRIAL DEMANDED

AND

ENDO HEALTH SOLUTIONS, INC.  
1400 ATWATER DRIVE  
MALVERN, PA 19355

AND

JANSSEN PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

JANSSEN PHARMACEUTICA, INC. N/K/A  
JANSSEN PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933

AND

ORTHO-McNEIL-JANSSEN  
PHARMACEUTICALS, INC. N/K/A JANSSEN  
PHARMACEUTICALS, INC.  
1125 BEAR TAVERN ROAD  
TITUSVILLE, NJ 08560

AND

PERNIX THERAPEUTICS HOLDINGS, INC.  
10 NORTH PARK PLACE, SUITE 201  
MORRISTOWN, NJ 07960

AND

PURDUE PHARMA, L.P.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND

PURDUE PHARMA, INC.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND

PURDUE FREDERICK COMPANY, INC.  
201 TRESSER BOULEVARD  
STAMFORD, CT 06901

AND

SHIONOGI, INC.  
300 CAMPUS DRIVE  
FLORHAM PARK, NJ 07932

AND

WEST-WARD PHARMACEUTICALS CORP.  
401 INDUSTRIAL WAY WEST  
EATONTOWN, NJ 07724

AND

ZOGENIX, INC.  
5858 HORTON STREET, SUITE 455  
EMERYVILLE, CA 94608

DEFENDANTS.

**NOTICE TO DEFEND**

**NOTICE:** You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objection to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

Philadelphia Bar Association, Lawyer Referral and Information Service  
1101 Market Street, Philadelphia, PA 19107 / (215) 238-6300

**AVISO:** Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las páginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades o otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELÉFONO A LA OFICINA CUYA DIRECCIÓN SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACIÓN DE LICENCIADOS DE FILADELFIA  
Servicio De Referencia E Información Legal  
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PURDUE PHARMA, L.P.  
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201 TRESSER BOULEVARD  
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SHIONOGI, INC.  
300 CAMPUS DRIVE  
FLORHAM PARK, NJ 07932

AND

WEST-WARD PHARMACEUTICALS CORP.  
401 INDUSTRIAL WAY WEST  
EATONTOWN, NJ 07724

AND

ZOGENIX, INC.  
5858 HORTON STREET, SUITE 455  
EMERYVILLE, CA 94608

DEFENDANTS.

### **COMPLAINT**

Plaintiff Iron Workers' District Council of Philadelphia and Vicinity Benefit Fund (the "FUND"), by and through its attorneys, ANAPOL WEISS and FRITZ & BIANCULLI, LLC, hereby brings this civil action seeking relief from Defendants Abbott Laboratories, Inc. ("ABBOTT"); AbbVie, Inc. ("ABBVIE"); Depomed, Inc. ("DEPOMED"); Endo Pharmaceuticals, Inc., Endo Health Solutions, Inc. (collectively, "ENDO"); Janssen Pharmaceuticals, Inc., Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals N/K/A Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc. (collectively, "JOHNSON & JOHNSON"); Pernix Therapeutics Holdings, Inc.

("PERNIX"); Purdue Pharma, L.P., Purdue Pharma, Inc., Purdue Frederick Company, Inc. (collectively, "PURDUE"); Shionogi, Inc. ("SHIONOGI"); West-Ward Pharmaceuticals Corp. ("WEST-WARD"); and Zogenix, Inc. ("ZOGENIX"),<sup>1</sup> and avers as follows upon the personal knowledge of the undersigned and their own acts and experiences, and as to all other matters, upon information and belief, including investigation conducted by its attorneys:

### INTRODUCTION

1. Despite well-recognized legal principles requiring DEFENDANTS to be truthful in their representations and marketing activities regarding their opioid-based pharmaceuticals, DEFENDANTS have engaged in an intentional, decades-long pattern of deceptive and misrepresentative conduct that has impermissibly obfuscated the grave medical risks associated with utilizing opioids pharmaceuticals created and/or marketed by DEFENDANTS to treat long-term and/or chronic pain<sup>2</sup> and similar medical conditions.

2. This unconscionable behavior has created a national epidemic of catastrophic proportions, with drug overdose now recognized as the leading cause of death for all Americans under 50.<sup>3</sup> In 2016 alone, approximately 4,642 overdose-related deaths were reported in the Commonwealth of Pennsylvania, meaning that an average of 13 Pennsylvanians died every day of the year (and with the presence of opioids confirmed in at least 85 percent of those incidents).<sup>4</sup> In Philadelphia City and County, alone, there were some 907 overdose-related deaths in 2016 (again, with the presence of opioids confirmed in

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<sup>1</sup> These entities will be collectively referred to as "DEFENDANTS" where appropriate and expedient.

<sup>2</sup> As utilized in this Complaint, "chronic pain" refers to non-cancer-based pain lasting three months, or longer.

<sup>3</sup> See, e.g., Sheila Kaplan, "C.D.C. Reports a Record Jump in Drug Overdose Deaths Last Year," THE NEW YORK TIMES, (November 3, 2017), available at <https://goo.gl/KaUFqn>.

<sup>4</sup> See, e.g., U.S. Drug Enforcement Agency & Univ. of Pittsburgh, "Analysis of Overdose Deaths in Pennsylvania, 2016," (July 2017), at 5, available at <https://goo.gl/i89z7x>.

more than 80 percent of those incidents).<sup>5</sup> Statewide and in Philadelphia, prescription opioids accounted for approximately 25 and 22 percent of those deaths, respectively.<sup>6</sup>

3. Even worse, overdose-related deaths increased in both the Commonwealth and Philadelphia by 27 and 29 percent, respectively, between 2015 and 2016.<sup>7</sup> These unprecedented spikes in overdose-related deaths tellingly coincide with equally unparalleled increases in opioid prescriptions: between 1999 and 2014, sales of prescription opioids quadrupled with a concomitant increase in the number of deaths related to prescription opioids.<sup>8</sup> Publicly available data indicates that abuse of prescription opioids is a contributing risk factor in the use of illegal narcotics (*e.g.*, heroin) and addiction.<sup>9</sup>

4. Despite DEFENDANTS' duty to represent truthfully (*i.e.*, not to misrepresent) the nature and efficacy of its pharmaceuticals, DEFENDANTS made misrepresentations about their drugs simply to earn more money and accumulate larger profits. DEFENDANTS' focus on profitability callously ignored (and ignores) the truth borne out in the grim statistics recited above. This reality is in large part, the natural consequences of DEFENDANTS' activities described herein.<sup>10</sup>

<sup>5</sup> *See, e.g.*, Philadelphia Dep't of Pub. Health, "2016 Overdoses From Opioids in Philadelphia," CHART, 2:7 (April 2017), at 1, available at <https://goo.gl/wg1TYL>.

<sup>6</sup> *See, e.g., supra* n.4 at 5, 90.

<sup>7</sup> *Id.*

<sup>8</sup> *See, e.g.*, Centers for Disease Control and Prevention, "Opioid Overdose: Prescribing Data," (August 30, 2017), available at <https://goo.gl/fYuS2o>.

<sup>9</sup> *See, e.g.*, Wilson M. Compton, M.D., *et al.*, "Relationship between Nonmedical Prescription-Opioid Use and Heroin Use," N. ENGL. J. MED. 374:2, at 160-61 (January 14, 2016) ("Available data indicate that the nonmedical use of prescription opioids is a strong risk factor for heroin use. . . . The transition from nonmedical use of prescription opioids to heroin use appears to be part of the progression of addiction . . . primarily among persons with frequent nonmedical use and those with prescription opioid abuse or dependence.").

<sup>10</sup> *See, e.g.*, Susan Okie, "A Flood of Opioids, a Rising Tide of Deaths," 363 NEW ENGL. J. MED. 1981 (2010) (concluding that opioid overdose deaths and prescriptions for opioids both increased roughly by 10-fold from 1990 to 2007).

5. Overall, DEFENDANTS have committed civil insurance fraud<sup>11</sup> and violated the common law of Pennsylvania. By flagrantly misrepresenting the efficacy of their own products and impermissibly minimizing the risks associated with the use of those same products, DEFENDANTS have caused significant and ascertainable harm to the FUND and its participants, retirees, and their dependents.

### **JURISDICTION AND VENUE**

6. This action has been commenced within the original subject matter jurisdiction of the Philadelphia County Court of Common Pleas pursuant to 42 P.S. § 931.

7. Overall, personal jurisdiction is proper in light of the general and specific contacts DEFENDANTS maintain with the Commonwealth of Pennsylvania. DEFENDANTS regularly and systematically transact business within Pennsylvania pursuant to 42 Pa.C.S. §§ 5322(a)(1)(i)-(v). Furthermore, ENDO maintains its principal places of business within the Commonwealth of Pennsylvania, and Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania. Thus, personal jurisdiction is properly exercised over DEFENDANTS.

8. Venue is proper in this Court pursuant to PA. R. CIV. P. 1006 as Philadelphia County is a county in which DEFENDANTS regularly and systematically conducts business and a county in which a substantial part of the events giving rise to the claims occurred.

### **THE PARTIES**

#### **PLAINTIFF (FUND):**

9. Plaintiff FUND is an employee benefit plan, with an office and principal place of business located at 2 International Plaza Driver, International Plaza Two, Suite 120, Philadelphia, PA 19113, and is thus a citizen of Pennsylvania. The FUND was established

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<sup>11</sup> 18 Pa.C.S. §4117(g).

with the explicit purpose of providing health and welfare benefits for covered lives, including employees and former employees (and their dependents) who pay into the FUND, and are represented by Iron Workers Locals 399, 401, 404, 405, and/or 451 for the purposes of collective bargaining. These benefits include, but are not limited to, a range of prescription drug benefit plans. Pursuant to the administration and management of these various plans and at all times relevant hereto, the FUND, through managed care administrators and others, purchased and purchases prescription drugs for the FUND's participants, retirees, and their dependents, or reimbursed the aforesaid individuals for their prescription drug purchases.

**ENDO:**

10. Defendant Endo Health Solutions, Inc. is a corporation organized under the laws of the State of Delaware and with its principal place of business and corporate headquarters located at 1400 Atwater Drive, Malvern, PA 19355.

11. Defendant Endo Pharmaceuticals Inc. is a corporation incorporated under the laws of the State of Delaware and with its principal place of business and corporate headquarters located at 1400 Atwater Drive, Malvern, PA 19355. It is a wholly owned subsidiary of Endo Health Solutions, Inc.

12. Upon information and belief, ENDO has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Opana ER** (oxymorphone hydrochloride): Schedule II opioid agonist extended-release tablet first approved in 2006 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate." Prior to April 2014, Opana ER was indicated for the "relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."

13. At all times relevant hereto, ENDO through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Opana ER throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**PURDUE:**

14. Defendant Purdue Pharma, L.P., is a limited partnership organized under the laws of the State of Delaware, and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.

15. Defendant Purdue Pharma, Inc., is a corporation organized under the laws of the State of Delaware, and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.

16. Defendant Purdue Frederick Company, Inc., is a corporation organized under the laws of the State of Delaware, and with its principal place of business and corporate headquarters located at 201 Tresser Boulevard, Stamford, CT 06901.

17. Upon information and belief, PURDUE has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **OxyContin** (oxycodone hydrochloride): Schedule II opioid agonist extended-release tablet first approved in 1995 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Prior to April 2014, OxyContin was indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.
- b. **Butrans** (buprenorphine): Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the

management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Prior to April 2014, Butrans was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”

- c. **Hysingla ER** (hydrocodone bitrate): Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate.

18. At all times relevant hereto, PURDUE through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed OxyContin, Butrans, and Hysingla ER (hereinafter, collectively “PURDUE Opioids”) throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**ABBOTT:**

19. Defendant Abbott Laboratories, Inc., is a corporation incorporated under the laws of the State of Illinois and with its principal place of business and corporate headquarters located at 100 Abbott Park Road, Abbott Park, Illinois 60064.

20. Upon information and belief, ABBOTT entered in to a co-promotion agreement with PURDUE in 1996. ABBOTT actively marketed PURDUE Opioids pursuant to that agreement from 1996 to 2002 in collaboration and conjunction with the concomitant efforts of PURDUE. Thereafter, ABBOTT received residual payments on the sale of PURDUE Opioids until 2006.

21. At all times relevant hereto, ABBOTT through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly advertised, promoted, marketed, sold, and distributed PURDUE Opioids throughout the



Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

**ABBVIE**

22. AbbVie, Inc. is a corporation organized under the laws of the State of Delaware, and with its corporate headquarters located at 1 North Waukegan Road, North Chicago, Illinois 60064.

23. Specifically, ABBVIE is the corporate remainder of ABBOTT taking the decision to essentially divide its corporate business, and spin-off its sales of pharmaceuticals (including opioids) into a separate corporate entity. ABBVIE is the resulting entity, and has carried on ABBOTT's marketing and manufacturing undertakings since January 1, 2013.

24. Upon information and belief ABBVIE has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Vicodin/Vicodin ES**<sup>12</sup> (hydrocodone bitartrate and acetaminophen): Schedule II opioid agonist tablet first approved in 1984 and 1991 (respectively) and both indicated for the relief of moderate to moderately severe pain.

25. At all times relevant hereto, ABBVIE through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Vicodin/Vicodin ES throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

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<sup>12</sup> Although marketed in different dosages, these two drugs are functionally identical.

**JOHNSON & JOHNSON:**

26. Defendant Johnson & Johnson is a corporation organized under the laws of the State of New Jersey and with its principal place of business and corporate headquarters located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

27. Defendant Janssen Pharmaceuticals, Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, and with its principal place of business and corporate headquarters located at 1125 Bear Tavern Road, Titusville, NJ 08560. It is a wholly owned subsidiary of Johnson & Johnson.

28. Defendant Ortho-McNeil-Janssen Pharmaceuticals N/K/A Janssen Pharmaceuticals, Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, and with its principal place of business and corporate headquarters located at 1125 Bear Tavern Road, Titusville, NJ 08560.

29. Defendant Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, and with its principal place of business and corporate headquarters located at 1125 Bear Tavern Road, Titusville, NJ 08560.

30. Upon information and belief, JOHNSON & JOHNSON has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Nucynta** (tapentadol): Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the “relief of moderate to severe acute pain in patients 18 years of age or older.”
- b. **Nucynta ER** (tapentadol extended release): Schedule II opioid agonist tablet first approved in 2011 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment

options are inadequate.” Prior to April 2014, Nucynta ER was indicated for the “management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults.” The DPN indication was added in August 2012.

- c. **Ultram** (tramadol hydrochloride): Schedule II opioid agonist tablet first approved in 1995 and indicated for the management of moderate to moderately severe pain in adults.

31. At all times relevant hereto, JOHNSON & JOHNSON through its corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Nucynta, Nucynta ER, and Ultram (hereinafter, collectively “J&J Opioids”), throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

#### **ZOGENIX & PERNIX**

32. Pernix Therapeutics Holdings, Inc. is a corporation organized under the laws of the State of Maryland, and with its corporate headquarters located at 10 North Park Place, Suite 201, Morristown, New Jersey 07960.

33. Zogenix, Inc. is a corporation organized under the laws of the State of Delaware, and with its corporate headquarters located at 5858 Horton Street, Suite 455, Emeryville, California 94608.

34. Upon information and belief PERNIX and ZOGENIX have both been (and PERNIX currently still is) developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Zohydro ER** (hydrocodone bitartrate): Schedule II opioid agonist extended-release tablet first approved in 2013 and indicated for the management of pain severe enough to require daily, around-the-

clock, long-term opioid treatment and for which alternative treatment options are inadequate.

35. Specifically, ZOGENIX originally obtained FDA approval for Zohydro ER in 2013, but thereafter sold their interest in the product to PERNIX in 2015. Upon information and belief, both ZOGENIX and PERNIX participated in the collusive marketing practices detailed throughout this complaint during their respective periods of ownership and control of Zohydro ER.

36. At all times relevant hereto, ZOGENIX and PERNIX through their respective corporate subsidiaries, authorized agents, servants, employees, and/or other representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Zohydro ER throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

#### **WEST-WARD**

37. West-Ward Pharmaceuticals Corp. is a corporation organized under the laws of the State of Delaware, and with its principal place of business located at 401 Industrial Way West, Eatontown, New Jersey 07724.

38. Upon information and belief WEST-WARD has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Roxicet** (oxycodone hydrochloride and acetaminophen): Schedule II opioid agonist tablet first approved in 1980 and indicated for the relief of moderate to moderately severe pain.

39. Roxicet was originally manufactured and marketed by Roxane Laboratories, Inc., but WEST-WARD's parent company (Hikma) acquired Roxane in 2015 and merged

Roxane into WEST-WARD (including ownership and control of Roxicet). Thus, WEST-WARD is both the successor-in-interest to Roxane and the current owner of Roxicet.

40. At all times relevant hereto, WEST-WARD through its corporate subsidiaries, authorized agents, servants, employees, and/or representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Zohydro ER throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND, and its participants, retirees, and their dependents.

#### **SHIONOGI**

41. Shionogi Inc. is organized under the laws of the State of Delaware, and with its corporate headquarters located at 300 Campus Drive, Florham Park, New Jersey 07932.

42. Upon information and belief SHIONOGI has been, and currently is, developing, marketing, advertising, promoting, and selling prescription pharmaceuticals in Philadelphia County and throughout Pennsylvania, including the following opioids:

- a. **Xodol** (hydrocodone bitartrate and acetaminophen): Schedule II opioid agonist tablet first approved in 2006 and indicated for the relief of moderate to moderately severe pain.

43. At all times relevant hereto, SHIONOGI through its corporate subsidiaries, authorized agents, servants, employees, and/or representatives regularly manufactured, advertised, promoted, marketed, sold, and distributed Xodol throughout the Commonwealth of Pennsylvania and the City and County of Philadelphia, including but not limited to the FUND and its participants, retirees, and their dependents.

#### **FACTUAL BACKGROUND**

##### **A. Opioids Have Limited Medically Approved Uses and Pose Severe Risks (Including Death and Addiction), Even Used Appropriately.**

44. The term "opioid" refers to and includes all natural, synthetic, and semi-synthetic substances that bind to and interact with the opioid receptors in the human brain.

This civil action implicates a specific subclass of opioids known as “opioid agonists,” which principally have an analgesic effect when taken for therapeutic purposes (*i.e.*, the relief of pain).<sup>13</sup> Pharmacologically, opioids interact with receptors located in the human brain and spinal cord, and are an effective option in the treatment of acute short-term pain (*e.g.*, surgery, traumatic injuries, and/or cancer) and the provision of end-of-life care.<sup>14</sup>

45. Despite these limited acceptable uses, opioids are essentially identical to narcotics like heroin and opium, in terms of pharmacological effect and the dangerously high risks for abuse,<sup>15</sup> development of dependence/tolerance, and addiction.<sup>16</sup> The abuse (and even the mere *use*) of opioids is also associated with the potential for severe physical side effects, including respiratory depression, coma, and death.<sup>17</sup>

46. Individuals using and/or abusing opioids in the long-term eventually develop tolerance (and, therefore, require ever-increasing dosages to continue to achieve the desired analgesic effect).<sup>18</sup> The diminishing returns of treatment make overdoses insidiously

<sup>13</sup> See, *e.g.*, Freye, Enno, “Part II. Mechanism of action of opioids and clinical effects,” *Opioids in Medicine: A Comprehensive Review on the Mode of Action and the Use of Analgesics in Different Clinical Pain States*, p. 85 (2008) (“Opioid is a general term that includes naturally occurring, semi-synthetic, and synthetic drugs, which produce their effects by combining with opioid receptors . . .”).

<sup>14</sup> See, *e.g.*, Nathaniel Katz, “Opioids: After Thousands of Years, Still Getting to Know You,” 23(4) CLIN J. PAIN 303 (2007); Roger Chou, *et al.*, “Research Gaps on Use of Opioids for Chronic Noncancer Pain,” 10(2) J. PAIN 147 (2009).

<sup>15</sup> See, *e.g.*, Wilson M. Compton & Nora D. Volkow, “Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies,” 81(2) DRUG & ALCOHOL DEPENDENCE 103, 106 (2006) (“[A] potential side effect from chronic use [of opioids] can be abuse and addiction . . . . In fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena.”).

<sup>16</sup> As used throughout this Complaint, the term “addiction” refers to the full spectrum of “substance abuse disorders” identified in the authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) (“DSM-V”), and encompasses behavior ranging from abuse/misuse of drugs, through physical and/or mental dependence, to addiction.

<sup>17</sup> See, *e.g.*, Letter from Janet Woodcock, M.D. to Andrew Kolodny, MD RE: Docket No. FDA-2012-P-0818 (September 10, 2013), at 2, available at <https://goo.gl/gfIdBu> (“Even proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.”).

<sup>18</sup> See, *e.g.*, Mitchell H. Katz, “Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith,” 170(16) ARCHIVES OF INTERNAL MED. 1422 (2010) (describing doses that are “frighteningly high”).

common,<sup>19</sup> while ceasing the use of opioids, altogether, risks severe withdrawal symptoms. Given the volatile potential for addiction and physical harm associated with even medically proper use, opioids have been regulated as controlled substances for decades.

47. Although generally effective in the treatment of short-term ailments, no controlled studies have ever established the efficacy (or safety) of using opioids in the treatment of chronic pain or other long-term conditions. Indeed, medical and pharmacological articles and studies produced during the 1970s, 1980s, and 1990s indicated a growing scientific consensus that opioids should be discouraged (or even prohibited), in the treatment of chronic pain:

The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuated reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.<sup>20</sup>

48. Continuing through until the present, medical evidence continues to establish that the long-term use of opioids produces rapidly diminishing analgesic benefits (if any)<sup>21</sup>

<sup>19</sup> See, e.g., "Opioid Overdose," CENTERS FOR DISEASE CONTROL AND PREVENTION, available at <https://www.cdc.gov/drugoverdose/index.html> (reporting that opioid-related overdoses accounted for more than 33,000 deaths in 2015, nearly half involving prescription drugs).

<sup>20</sup> Russell K. Portenoy, "Opioid Therapy for Chronic Nonmalignant Pain: Current Status," 1 PROGRESS IN PAIN RES. & MGMT. 247 (1994).

<sup>21</sup> See, e.g., Andrea D. Furlan, *et al.*, "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects, 174(11) CAN. MED. ASS'N J. 1589 (2006); Eriksen J., *et al.*, "Critical issues on opioids in chronic non-cancer pain," 125 PAIN 172, 172-79 (2006) (concluding that chronic pain patients taking opioids self-scored themselves lower in terms of body pain, physical function, mental function, social function, and vitality).

and diminishes patients' overall health.<sup>22</sup> Indeed, prior to the acts of DEFENDANTS complained of herein "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids."<sup>23</sup>

49. The widely recognized therapeutic restrictions discussed above significantly limit (or, *should* limit) the available Patient Population Market<sup>24</sup> for the marketing and sale of opioids. Put simply, the medical consensus that opioids are ineffective (and, in fact, gravely dangerous) when used to treat long-term conditions and/or chronic pain was nothing more than an economically inconvenient truth to the DEFENDANTS.

**B. DEFENDANTS' Marketing Campaigns Proliferated Dangerous Misperceptions That "Chronic Opioid Therapy" is Effective and Safe.**

50. Solely in the service of achieving dramatic growth in sales and revenue, DEFENDANTS individually (and, in many instances, cooperatively) undertook concerted efforts to alter the medically accepted standard of care regarding opioids. In particular, DEFENDANTS were concerned with persuading both patients and doctors that opioids are effective and safe in the treatment of common, chronic pain conditions (*e.g.*, headaches, joint pain/arthritis, back/knee pain, *etc.*) and similar medical conditions (hereinafter, "chronic opioid therapy").

51. DEFENDANTS created an entire market from whole cloth by promoting the false efficacy of chronic opioid therapy. DEFENDANTS also endeavored to impermissibly minimize and obfuscate the risks associated with opioid use, including but not

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compared to non-opioid patients); Dillie K.S., *et al.*, "Quality of life associated with daily opioid therapy in a primary care chronic pain sample," 21 J. AM. BD. FAM. MED. 108, 108-17 (2008).

<sup>22</sup> See, *e.g.*, Andrea Rubenstein, "Are we making pain patients worse?" SONOMA MEDICINE (Fall 2009), available at <https://goo.gl/SpqD2P> ("[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.").

<sup>23</sup> Igor Kissin, "Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?" 6 J. PAIN RESEARCH 513, 514 (2013).

<sup>24</sup> Term of art referring to the projected market (*i.e.*, potential patients) for various pharmaceutical products.



limited to addiction/dependence, development of tolerance, infection, and death. Overall, DEFENDANTS valued profit more than the public health, and were concerned with safeguarding their bottom line, as opposed to the well-being of their Pennsylvania patients and customers, including the FUND.

52. DEFENDANTS shared a purpose in undertaking their respective campaigns of disinformation, and their methods bespeak certain commonalities as well. Individually and collectively, DEFENDANTS engaged in behaviors that created and proliferated dangerously misleading impressions amongst doctors and patients, which: (i) misrepresented opioids as generally safe for use by most patients; (ii) misrepresented and exaggerated the efficacy of “chronic opioid therapy;” (iii) impermissibly minimized the risks of addiction/dependence/tolerance posed by the use of opioids, including creation and proliferation of the concept of “pseudoaddiction”;<sup>25</sup> (iv) misrepresented the ability of so-called “screening tools” to identify patients at risk of addiction/dependence; (v) misrepresented and impermissibly minimized the grave risks of taking ever-higher doses of opioids to maintain long-term pain relief; (vi) misleadingly portrayed and enlarged the risks associated with opioid competitors, such as non-steroidal anti-inflammatory drugs (“NSAIDs”); and (vii) misrepresented that chronic opioid therapy permits patients to resume their regular lives, improves functionality, and/or improves overall quality of life.

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<sup>25</sup> This insidious term was originally coined in a 1989 article suggesting that patients exhibiting behaviors typically associated with opioid addiction were actually suffering from “pseudoaddiction” due to medical undertreatment of patients’ pain. *See, e.g.*, Marion S. Greene & R. Andrew Chambers, “Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature,” *CURR. ADDICTION REP.* (2015) 2(4), at 310-17, *available at* <https://goo.gl/Cqf5UK>. In recent years, this concept has been largely discredited by the medical and academic communities. *Id.* (“Pseudoaddiction is a quarter-century-old concept that has not been empirically verified. . . . The reliability of this conceptualization seems to hinge on the assumption that addiction and pain do not co-occur . . . . However, it is not the case that pain and addiction are mutually exclusive conditions, and no clear evidence exists that having pain protects against the genesis or expression of addiction.”).

53. Beginning in the late 1990s and continuing until the present, DEFENDANTS engaged in deceptive, unfair, and misleading campaigns to reverse the popular and medical understanding that opioids are inappropriate for the treatment of long-term and/or chronic pain. To accomplish this wholesale reversal, DEFENDANTS undertook numerous initiatives either directly, or through their agents, employees, servants, and/or representatives, including but not limited to:

- a. developing and disseminating seemingly truthful, purportedly educational materials and advertisements that misrepresented the risks, benefits, and superiority of DEFENDANTS' opioids and chronic opioid therapy;
- b. deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the risks, benefits, and superiority of DEFENDANTS' opioids and chronic opioid therapy;
- c. recruiting, funding, assisting, encouraging, and/or directing third-party, seemingly neutral physicians to act as paid speakers on behalf of DEFENDANTS' opioids and chronic opioid therapy, and to deliver scripted talks, draft misleading studies, present deceptive and misleading continuing medical education programs ("CMEs"), and serve on the boards and committees of professional societies and patient advocacy groups that promulgate guidelines supporting the use of opioids and chronic opioid therapy, (hereinafter, "key opinion leaders" or "KOLs"), including but not limited to David Haddox, Lynn R. Webster, Russell Portenoy, Kathleen Foley, Christine A. Miaskowski, Michael J. Brennan, Perry Fine, Scott Fishman, Lisa Weiss; Steven Stanos; and Daniel Bennett;
- d. funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (hereinafter, "Front Groups") that developed educational materials and treatment guidelines that were distributed by, or with assistance from, DEFENDANTS, which urged physicians to prescribe (and patients to use) DEFENDANTS' opioids, or to otherwise utilize chronic opioid therapy.

54. Although the efforts and purpose were common amongst DEFENDANTS, many of their individual actions also bear appropriately individual scrutiny.

i. **ENDO**

55. ENDO's misleading course of conduct that is generally described above was pervasive and focused primarily on the promotion of Opana ER. Upon information and belief, between 2007 and 2013, ENDO spent between \$3 million and \$10 million each quarter to promote the sales of Opana ER.

56. ENDO's dissemination of misleading materials included branded and non-branded books and pamphlets that were held out as nominatively medical and/or scientific (but, in fact, flagrantly misrepresented accepted medical science regarding chronic opioid therapy and were intended solely to drum-up sales of Opana ER).

57. One such publication was the 2007 book *Avoiding Opioid Abuse While Managing Pain*, which erroneously claims that "[o]pioids offer safe, effective treatment for many chronic pain conditions and pose little risk for addiction for most patients who take them to control pain."<sup>26</sup> The same publication also dangerously emphasizes that aberrant and/or drug-seeking behaviors (*i.e.*, potential evidence of addiction) in patients prescribed opioids should be regarded as evidence of "pseudoaddiction" and that increasing dosages should be the first clinical response. It also makes erroneous claims regarding the efficacy of chronic opioid therapy and gravely misrepresents chronic opioid therapy as a moral imperative on par with a human's ongoing need for sustenance.<sup>27</sup> Upon information and belief, Plaintiff avers that ENDO provided research and financial support and assisted in the distribution of *Avoiding Opioid Abuse While Managing Pain*, as well as providing consulting fees, *honoraria*, or other recompense to its authors and editors.

<sup>26</sup> See, e.g., Lynn R. Webster, MD & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*, (2007), relevant excerpt available at <https://goo.gl/K8Rx9h>.

<sup>27</sup> *Id.* ("Managing treatment with pharmaceutical analgesics is similar to managing an eating disorder. A person with problems managing food intake cannot solve the problem with abstinence, because eating is necessary for survival. . . . Similarly, society cannot eliminate the use of opioids, even though they can harm some consumers.").

58. ENDO also supported the publication and distribution of a pamphlet titled “Understanding Your Pain: Taking Oral Opioid Analgesics,” which makes outlandish claims along similar claims. In sum, the pamphlet: (i) implies that addiction is not related to the use of opioids, stating that “[a]ddicts take opioids for other reasons [other than pain relief], such as unbearable emotional problems” and that patients taking opioids for the management of pain are not generally at risk of addiction;<sup>28</sup> (ii) misstates the therapeutic limits of chronic opioid therapy, recklessly claiming that such dosages can merely be increased without limitation or consequence;<sup>29</sup> (iii) encourages patients to take pre-emptive opioid doses, advising that patients should “[k]eep on top of [their] pain—don’t wait until pain becomes severe to take your medicine;”<sup>30</sup> and (iv) advises patients to consider taking both long-acting opioids and short-acting opioids in conjunction with one another.<sup>31</sup>

59. Upon information and belief, Plaintiff avers that ENDO provided research and financial support and assisted in the distribution of “Understanding Your Pain: Taking Oral Opioid Analgesics,” as well as providing consulting fees, *honoraria*, or other recompense to its authors and editors.

60. ENDO also provided material, financial, and distributive support in the drafting, publication, and dissemination of articles in medical journals extolling the illusory virtues of chronic opioid therapy and misrepresenting the related risks.<sup>32</sup>

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<sup>28</sup> See, e.g., Margo McCaffery & Chris Pasero, ed. Russell K. Portenoy, “Understanding Your Pain: Taking Oral Opioid Analgesics,” ENDO PHARMACEUTICALS (2004), at 2, available at <https://goo.gl/DnUxRC>; see also, e.g., Endo Pharmaceuticals, “Living With Someone with Chronic Pain” (“Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”).

<sup>29</sup> *Id.* at 3.

<sup>30</sup> *Id.* at 4.

<sup>31</sup> *Id.*

<sup>32</sup> See, e.g., Endo Pharmaceuticals, “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain,” 5 PAIN MEDICINE NEWS 2, at 12-13 (March/April 2007) (describing massive gastrointestinal bleeds resulting from the use of NSAIDs and recommending the use of opioids due to their purported and alleged lack of adverse side effects).

61. ENDO's marketing efforts also included a significant online presence. Upon information and belief, ENDO sponsored, supported, and/or maintained at least two separate websites ([PainKnowledge.com](http://PainKnowledge.com) and [PainAction.com](http://PainAction.com)) which included averments that "[p]eople who take opioids as prescribed usually do not become addicted" and that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them." The websites were operative as of 2009 and 2011, respectively.

62. In addition to these publication-based marketing efforts, ENDO also engaged in direct misleading marketing representations through its sales representatives, including spoken representations and the distribution and publication of promotional and educational materials. Upon information and belief, those representations equally and similarly misrepresented the efficacy of Opana ER, chronic opioid therapy, and the risks related with such treatment options.

63. ENDO also recruited and supported "high" (*i.e.*, frequent) prescribers of Opana ER and other similarly situated physicians to serve as KOLs in order to win influence and prestige for the Opana ER within the medical community. The precise nature and extent of ENDO's Speakers' Bureau and its cultivation of KOLs is unknown to Plaintiff, but is uniquely known to ENDO. Upon information and belief, ENDO approached and retained numerous KOLs in its marketing of the Opana ER (and chronic opioid therapy) and utilized them in the manner described in this Complaint. In 2008 alone, ENDO spent nearly \$4 million to promote approximately 1,000 speaker programs around the country.

64. Prominent examples of ENDO KOLs include Russell Portenoy and Lynn Webster, both of whose work is substantively cited above. To his credit, Dr. Portenoy has since admitted that his actions were responsible for spreading "misinformation" and that he

“gave innumerable lectures in the late 1980s and 90s about addiction that weren’t true.”<sup>33</sup>

Dr. Webster was responsible both for the development of a cursory (and ineffective) diagnostic tool called the “Opioid Risk Tool” (*i.e.*, a five-question, one-minute questionnaire) that was purportedly useful in predicting a person’s risk for developing opioid addiction. Dr. Webster was also responsible for disseminating, at ENDO’s behest, various materials regarding so-called “pseudoaddiction,” a term and “condition” that even Dr. Webster has since admitted “became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept.”<sup>34</sup>

65. Upon information and belief, ENDO’s KOLs adhered to ENDO’s dictated “messaging,” which included the creation, distribution, and presentation of articles, publications, medical materials, diagnostic supplements, and CME materials<sup>35</sup> that misrepresented the nature of Opana ER and chronic opioid therapy.

66. ENDO also utilized, co-opted, appropriated, infiltrated, usurped and/or created so-called professional and patient advocacy Front Groups to amplify the reach of its illicit marketing activities, including the American Pain Foundation (the “APF”), the National Initiative on Pain Control (the “NIPC”), the Federation of State Medical Boards (the “FSMB”), the American Pain Society (the “APS”), the American Academy of Pain Medicine (the “AAPM”), and the American Geriatric Society (the “AGS”). ENDO utilized these third-party professional organizations in a variety of ways, including, but not limited to, publishing and popularizing so-called “guidelines” for chronic opioid therapy, publishing

<sup>33</sup> Thomas Catan & Evan Perez, “A Pain-Drug Champion Has Second Thoughts,” THE WALL STREET JOURNAL (Dec. 17, 2012).

<sup>34</sup> John Fauber & Ellen Gabler, “Networking Fuels Painkiller Boom,” THE MILWAUKEE WISCONSIN JOURNAL SENTINEL (Feb. 19, 2012).

<sup>35</sup> See, e.g., ENDO PHARMACEUTICALS, “Pain Management Dilemmas in Primary Care: Use of Opioids,” JOURNAL OF FAMILY PRACTICE (2007) (minimizing the risks of opioid addiction and misrepresenting that potential opioid patients at risk for addiction could be effectively prescreened). In particular, this CME material emphasized the use of erroneous and ENDO-created diagnostic “tools” like the Opioid Risk Tool.

and popularizing articles, educational materials, and promotional materials that were supportive of Opana ER and/or chronic opioid therapy, and supporting and publicizing the work and viewpoints of ENDO KOLs

67. ENDO worked closely with the APF (and its subsidiary the NIPC), providing substantial support to both organizations, exercising editorial control over their content, and taking a substantial role in the variety of misleading and deceptive messages, promotional materials, marketing, and educational products promulgated by APF and/or NIPC at the behest of ENDO. These initiatives included, but are not limited to: (i) creation of misleading CME materials, such as “Persistent Pain in the Older Patient” and “Persistent Pain in the Older Adult,” which misstated that elderly patients presented a decreased risk of addiction compared to younger patients; (ii) materially supporting, collaborating on the creation of and reviewing the materials posted on the NIPC website [PainKnowledge.com](http://PainKnowledge.com), which misrepresented that chronic opioid therapy had the potential to improve patients’ ability to function and quality of life; and (iii) the publication of “Exit Wounds,” a highly deceptive and misrepresentative publication aimed at veterans that stated that use of opioids increases functionality and minimized the risks of addiction.

68. In concert with ENDO, the FSMB created “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain” in 1998 and 2004. The Guidelines were thereafter used in 2007 to create a book titled “Responsible Opioid Prescribing,” which was also produced in conjunction with ENDO. Overall, these publications represented (and continue to represent) the use of opioids in the treatment of chronic pain as “essential.” The

publications, and in particular the 2007 book, were widely distributed by the FSMB to state medical boards and practicing doctors.<sup>36</sup>

69. With substantial support and the assistance of ENDO KOLs, the APS and the AAPM issued consensus guidelines in both 1997 and 2009 endorsing the use of opioids in the treatment of chronic pain and minimizing the resulting risks of addiction. The 2009 guidelines were widely publicized, and continue to be cited and republished.

70. In concert with ENDO, the AGS created and disseminated guidelines for the use of opioids for treating chronic pain in 2002 (“The Management of Persistent Pain in Older Persons”) and 2009 (“Pharmacological Management of Persistent Pain in Older Persons”). In particular, the 2009 Guidelines advised, without citation to any authoritative source, that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The 2009 Guidelines also advised that the risks of addiction resulting from chronic opioid therapy “are exceedingly low in older patients with no current or past history of substance abuse.”<sup>37</sup>

71. Reviewing the conclusions of these Front Groups, such as those described above, is also illustrative when viewed in stark contrast to similar guidance issued by an *independent* professional medical organization during the same time frame:

“The recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it. . . . [T]herapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health

<sup>36</sup> Although the 2012 revision no longer recommends chronic opioid therapy as a “first-line” treatment, it does continue to promote the concept of “pseudoaddiction” and managing addiction risk via screening.

<sup>37</sup> See, e.g., “Pharmacological Management of Persistent Pain in Older Persons,” 57 J. AM. GERIATRICS SOC’Y 1331, 1339, 1342 (2009).



risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.”<sup>38</sup>

72. By utilizing third-parties in order to present its questionable viewpoints and misrepresentative “research,” ENDO also created the false perception that the misrepresentations utilized by ENDO were the result of independent, objective research. Thus, it was far more likely to influence the opinions of patients, prescribers, and payors. To date, no reliable scientific data supports the marketing claims advanced by ENDO regarding opioids, chronic opioid therapy, or Opana ER. In fact, as demonstrated by the discussion above, much scientific research directly refutes ENDO, and some of ENDO’s own KOLs and Front Groups have since abandoned their previous positions.

73. The sequence of events surrounding ENDO’s recent application (and subsequent denial) of the approval of an allegedly reformulated version of Opana ER by the FDA is particularly instructive. Specifically, between 2011 and 2012 ENDO rolled out a reformulated version of Opana ER that was, according to ENDO “resistant to crushing” and possessed “properties that make it difficult to manipulate [it] into a soluble form that could be easily drawn into a syringe and subsequently injected by potential abusers.” Overall, this reformulation was intended to address concerns regarding the potential for abuse under the original formulation of Opana ER.

74. On November 30, 2012, ENDO submitted a citizen petition to the FDA in a bid to forestall the release of a generic version of Opana ER (and cancel all other similarly approved generics) under the rationale that the reformulated version was abuse-deterrent.

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<sup>38</sup> See, e.g., Laxmiah Manchikanti, *et al.*, “Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain,” American Society of Interventional Pain Physicians, available at <https://goo.gl/f85L9w>; see also, e.g., U.S. DEPT OF VETERANS AFFAIRS & U.S. DEPT OF DEFENSE, “Clinical Guidelines on Management of Opioid Therapy for Chronic Pain,” (May 2010) available at <https://goo.gl/Wxg6B5> (confirming the “lack of solid evidence based research on the efficacy of long-term opioid therapy”).

75. On May 10, 2013, the FDA denied ENDO's petition, concluding that reformulated Opana ER carried neither additional safety advantages nor sufficiently abuse-deterrent properties that necessitated or justified the relief requested (*i.e.*, the inclusion of FDA-approved labeling stating that Opana ER was effectively abuse-deterrent).

76. Between May 2013 and June 2017, the regulatory position of Opana ER concerning its potential for abuse and contribution to the opioid crisis continued to deteriorate, markedly. On June 8, 2017, the FDA issued a press release that requested ENDO to remove Opana ER, voluntarily, or face formal removal proceedings:

Today, the U.S. Food and Drug Administration requested that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market. After careful consideration, the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse.

\* \* \*

The FDA's decision is based on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation. Injection abuse of reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy). . . .

Opana ER was first approved in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. In 2012, Endo replaced the original formulation of Opana ER with a new formulation intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting. While the product met the regulatory standards for approval, the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER. Now, with more information about the risks of the reformulated product, the agency is taking steps to remove the reformulated Opana ER from the market.

\* \* \*

The FDA has requested that the company voluntarily remove reformulated Opana ER from the market. Should the company choose not to remove the product, the agency intends to take steps to formally require its removal by withdrawing approval. In the interim, the FDA is making health care professionals and others aware of the particularly serious risks associated with the abuse of this product.<sup>39</sup>

77. Despite this first of its kind regulatory action by the FDA in seeking the immediate and outright removal of Opana ER, the unabridged discussion above demonstrates that this is merely the latest in a decades-long course of conduct propagated by ENDO to the detriment of Plaintiff.

78. The same day that the FDA issued this request for the voluntarily withdrawal of Opana ER from the pharmaceuticals market, ENDO issued a defiant press release stating that “[T]his request does not indicate uncertainty with the product’s safety or efficacy when taken as prescribed.”<sup>40</sup> ENDO took no decisive action and, upon information and belief, continued the marketing and sale of Opana ER despite the FDA’s request for withdrawal.

79. On July 6, 2017—and following extensive negotiations with the FDA and a near-month of public pressure—ENDO was forced to concede that despite ENDO’s apparent continued belief “in the safety, efficacy, and favorable benefit-risk profile” of Opana ER, it would finally discontinue the product (but only after netting at least \$194.6 million in profit from their sales of Opana ER up to that point, while the discontinuance of ultimately cost ENDO only \$20 million in pre-tax charges).<sup>41</sup>

ii. **PURDUE:**

<sup>39</sup> U.S. FOOD & DRUG ADMIN., “FDA requests removal of Opana ER for risks related to abuse,” (June 8, 2017), available at <https://goo.gl/M3CE9z>.

<sup>40</sup> “Endo Response to June 8, 2017 FDA Meeting Related to OPANA® ER,” ENDO PHARMACEUTICALS, (June 8, 2017), available at <https://goo.gl/7GJ2wF>.

<sup>41</sup> “Endo Provides Update On OPANA® ER,” ENDO PHARMACEUTICALS, (July 6, 2017), available at <https://goo.gl/7rTqFV>.

80. PURDUE's misleading course of conduct was pervasive and focused primarily on the promotion of OxyContin (upon information and belief, PURDUE's marketing efforts extended to and included *all* of the PURDUE Opioids identified above).

81. PURDUE's support, synthesis, and proliferation of deeply misleading, purportedly medical and/or scientific materials included advertisements in scholarly journals. As a mere example, PURDUE ran an OxyContin advertisement in a 2005 issue of the *Journal of Pain* that promoted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a dramatization of a man and young boy fishing, with the epithet: "There Can Be Life With Relief." This depiction falsely implied that OxyContin is effective at both long-term pain relief and functional improvement of overall health—claims that are wholly unsubstantiated.

82. PURDUE also regularly advertised in both the *Journal of Pain* and the *Clinical Journal of Pain*, touting false claims suggesting that OxyContin was convenient for both patients and doctors because the drugs were effective for twelve (12) hours at a time (*i.e.*, Q12H). In reality, an allegedly Q12H dose of OxyContin does not provide the complete twelve (12) hours of relief that PURDUE claimed, but instead required consistently higher and more frequent dosages to achieve the same level of pain relief in the long-term (*i.e.*, in the treatment of so-called "chronic" conditions). Upon information and belief, Plaintiff asserts that Q12H OxyContin was much more rapidly absorbed (*i.e.*, depleted) than advertised by PURDUE, which was meant to increase the necessary doses required to provide adequate pain relief.

83. PURDUE also published books<sup>42</sup> and pervasively distributed pamphlets that misrepresented the efficacy of and risks associated with PURDUE Opioids and chronic opioid therapy. For example, PURDUE nationally published and distributed a nominally medical and/or scientific pamphlet geared towards law enforcement and prescribers titled “Providing Relief, Preventing Abuse,” which both impermissibly focused on the allegedly isolated incidents of OxyContin being abused via injection, while ignoring other common signs of addictive behavior (*i.e.*, asking for early refills or increased dosages). Moreover, this pamphlet emphasized the scientifically bereft term “pseudoaddiction” to explain potential drug-seeking behavior (and omitting that the concept of “pseudoaddiction” has been roundly rejected by the medical and scientific communities). PURDUE’s nefarious invocation of the term “pseudoaddiction” suggests that addictive behavior can be solved by “completely” treating a patient’s underlying chronic pain (*i.e.*, prescribing more opioids).

84. As a further example, PURDUE disseminated a mailer titled “Pain Vignettes” in 2012 that contained purported individual testimonies of OxyContin patients whose overall functionality and quality of life had been improved by a regular prescription of OxyContin. These claims fly in the face of the well-established medical consensus that long-term use of opioids does not improve life quality or overall functionality.

85. PURDUE’s marketing efforts also encompassed a significant online presence with PURDUE sponsoring, supporting, and/or maintaining at least two separate websites: In the Face of Pain and Partners Against Pain. These unbranded websites continued to press PURDUE’s major argument that the use of PURDUE Opioids (and OxyContin, in particular) were somehow essential to the effective treatment of chronic pain, and labeled

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<sup>42</sup> See, e.g., Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide*, (2007) (produced by the FSMB with significant support from PURDUE and other opioid manufacturers).

skepticism regarding such uses of opioids as being the result of “inadequate understanding” that leads to “inadequate pain control.”

86. In the Face of Pain openly criticized policies that limited access to opioids as being “at odds with best medical practices” and encouraged patients to be “persistent” in finding doctors willing to treat their pain (*i.e.*, prescribed opioids). In the Face of Pain was a gateway for deceptive clinical trials, medical information, and deceptive testimony from seemingly neutral “Advocates” who were actually heavily compensated KOLs and/or patients procured and directed by PURDUE.<sup>43</sup>

87. Similarly, PURDUE utilized its website Partners Against Pain to digitally distribute its 2005 pamphlet titled “Clinical Issues in Opioid Prescribing,” which claimed that “illicit drug use and deception” did not indicate an underlying addiction, but merely meant that the patient’s pain was undertreated: “Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.” In other words, prescribers confronted with potentially addictive behavior from patients should prescribe more opioids, and turning addiction into nothing more than an excuse to sell ever-increasing amounts of PURDUE Opioids.

88. At a higher level, PURDUE also sought to distort the state of medical literature regarding chronic opioid therapy by training its sales representatives to cite, amongst other things, a widely discredited letter-to-the-editor<sup>44</sup> discussing anecdotal observations regarding “narcotics” and addiction. PURDUE’s support and proliferation of

<sup>43</sup> See, e.g., Purdue Pharmaceuticals, “In the Face of Pain® Offers New Tools and Resources to Patients, Caregivers and Healthcare Professionals Advocating for Better Pain Care,” (September 22, 2011), available at <https://goo.gl/vZGd6v>.

<sup>44</sup> See, e.g., Jane Porter & Hershel Jick, “Addiction Rare in Patients Treated with Narcotics,” 302(2) NEW ENG. J. MED. 123 (January 10, 1980) (“We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.”).

this misconception was manifested by its sales representatives and publications relying upon this source for unsupported and erroneous claims that the risk of addiction among patients being treated with PURDUE Opioids was greatly diminished.<sup>45</sup>

89. Along similar lines, PURDUE caused a separate study that they had sponsored which ultimately concluded that OxyContin had addiction rates between 8 and 13 percent to be buried in headache-specific literature, so as to minimize its impact.<sup>46</sup>

90. In addition to these indirect marketing efforts, PURDUE also engaged in direct misleading marketing representations through its sales representatives,<sup>47</sup> including spoken representations, the distribution and publication of promotional and educational materials, and telephone solicitations. Upon information and belief, PURDUE continued to contact doctors/prescribers in support of PURDUE Opioids even after those same individuals/entities were placed on “do not call” lists.

91. Upon information and belief, PURDUE employed some 250 sales representatives in 2007 alone, of whom a full 150 were entirely devoted to promoting OxyContin. In 2014, alone, PURDUE spent \$108 million on such direct sales efforts. Upon information and belief, Plaintiff avers that those direct sales materials, representations, and solicitations also misrepresented the efficacy of PURDUE Opioids and the risks

<sup>45</sup> See, e.g., Art Van Zee, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,” 99(2) AM. J. PUB. HEALTH 221 (2014), available at <https://goo.gl/IqWcGA>; see also, e.g., C. Peter N. Watson, *et al.*, “Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy,” 105 PAIN 71 (2003) (citing the Porter & Jicks letter to support the notion that OxyContin is not typically addictive).

<sup>46</sup> See, e.g., Lawrence Robbins, “Long-Acting Opioids for Severe Chronic Daily Headache,” 10(2) HEADACHE QUARTERLY 135 (1999); see also, e.g., Lawrence Robbins, “Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache,” 19 HEADACHE QUARTERLY 305 (1999).

<sup>47</sup> PURDUE targeted individual prescribers and tracked their prescribing habits. These efforts included a secret monitoring program that, over the course of nine years, identified some 1,800 doctors whose prescribing habits demonstrated a high probability that they were writing prescriptions of PURDUE Opioids for addicts and drug dealers. A separate lawsuit filed in the Superior Court of the State of Washington for Snohomish County details that PURDUE was readily able to identify doctors that were operating so-called “pill mills,” and took no action to shut down their proverbial “gold mines.” See, e.g., Complaint, *City of Everett v. Purdue Pharma, L.P.*, et al., Case No. 17-2-00469-31, at ¶¶ 46-61 (January 19, 2017).

associated with chronic opioid therapy. Overall, these marketing efforts ultimately had a substantial and pervasive impact on the regularity with which doctors prescribed OxyContin and the other PURDUE Opioids to their patients.<sup>48</sup> Moreover, PURDUE has been ramping up its promotional efforts in recent years—between 2007 and 2014, PURDUE’s quarterly promotional spending increased from under \$5 million to more than \$30 million.

92. PURDUE also recruited, trained, supported, paid, and utilized high prescribers of PURDUE Opioids and other similarly situated physicians to serve as KOLs in order to win influence and prestige for the PURDUE Opioids within the medical community. Upon information and belief, these KOLs adhered to PURDUE’s dictated “messaging.” PURDUE’s efforts also included the creation, distribution, and presentation of medical supplements and CME materials that misrepresented the nature of Purdue Opioids and chronic opioid therapy, and similar initiatives.

93. The precise nature and complete extent of PURDUE’s cultivation of medical KOLs is unknown to Plaintiff, but is uniquely known to PURDUE. Upon information and belief, PURDUE approached and retained numerous KOLs in its marketing of the PURDUE Opioids and utilized them in the manner described in this Class Action Complaint. Prominent examples of these KOLs include Dr. David Haddox, Dr. Russell Portenoy, and Dr. Lynn Webster. In particular, Dr. Haddox began as a paid PURDUE speaker and ultimately became PURDUE’s Vice President of Risk Management—he was responsible for coining the misleading phrase “pseudoaddiction,” although it was ultimately popularized by Drs. Portenoy and Webster, along with others.

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<sup>48</sup> See, e.g., Art Van Zee, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,” 99(2) AM. J. PUB. HEALTH 221 (2014) (identifying a correlation between the increase in OxyContin prescriptions from 670,000 in 1997 to 6.2 million in 2002 and PURDUE’s doubling of its sales force and trebling of its annual sales calls), available at <https://goo.gl/gp3qQh>.



94. Much of the efforts of PURDUE's KOLs were aimed at influencing prescribing doctors via seminars and CME presentations that were sponsored, underwritten, or otherwise supported by PURDUE, including: (i) a 2011 webinar taught by Dr. Lynn Webster titled "Managing Patient's Opioid Use: Balancing the Need and Risk," which relied heavily on concepts like pseudoaddiction and instructed doctors that "screening tools" like the Opioid Risk Tool and written treatment agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths;" (ii) a February 2012 CME program titled "Safe Opioid Prescribing," which continued to cite the aforementioned 1980 letter-to-the-editor and also falsely emphasized the "competing public health crisis of undertreated pain and prescription drug use;" (iii) a October 2012, PURDUE-sponsored CME titled "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which recommended that the use of "screening tools," more frequent refills, and switching between different opioid formulations could treat high-risk patients who are showing signs of potentially addictive behavior; (iv) a CME titled "Path of the Patient: Managing Chronic Pain in Younger Adults at Risk for Abuse," which suggested that younger chronic opioid therapy patients who are at-risk for addiction may simply be suffering from pseudoaddiction; and (v) a series of CMEs titled "Overview of Management Options," which were issued by the American Medical Association and suggested that opioid alternatives (*i.e.*, NSAIDs) are dangerous at high doses, but which omitted opioids from similar analysis (and despite definitive medical evidence establishing the well-documented risks of treatment via opioids).

95. Defendants have also utilized, co-opted, appropriated, infiltrated, usurped and/or created so-called Front Groups to amplify the reach of its illicit marketing activities, including APF, FSMB, APS, AAPM, and AGS.

96. PURDUE exercised tremendous and constant control over the efforts and conduct of the APF, which were explicitly intended and directed to complement and support PURDUE's own marketing efforts. Pursuant to a "Master Consulting Services Agreement" executed on September 14, 2011, PURDUE was granted contractual editorial and administrative oversight over APF's promotional efforts as well as the unilateral right to terminate the agreement at their discretion.

97. Upon information and belief, PURDUE utilized APF to support its misrepresentative and fraudulent marketing efforts in the following ways: (i) hiring an APF consultant to conduct work on the rollout of the Partners Against Pain website; (ii) hiring an APF consultant to conduct work and promotion of one of PURDUE's opioid-related projects, "Understanding & Coping with Lower Back Pain;" (iii) obtaining "patient representatives" to provide testimonials on "Partners Against Pain;" (iv) soliciting and/or requiring APF board members (including Dr. Lynn Webster) and other PURDUE KOLs and patients to appear on In the Face of Pain as "champions passionate about making a difference in the lives of people who live with pain" (while in fact the parties were well-compensated for their appearances); (v) requiring APF to cede control of its highly influential Pain Care Forum ("PCF") to PURDUE's in-house lobbyist Burt Rosen so that the group's efforts could be directed solely for PURDUE's benefit; (vi) utilizing the PCF to undermine any requirements that prescribers attend CMEs addressing best-practices in the area of chronic opioid therapy; and (vii) utilizing the PCF to parrot PURDUE's own misrepresentative marketing campaign, including the following statement: "[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer patients without prior histories of substance abuse using the medication as directed is rare.

Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug.”<sup>49</sup>

98. PURDUE also collaborated extensively with APF in the publication of various supplements, providing substantial support to the organization and exercising editorial control over content, including: (i) “A Policymaker’s Guide to Understanding Pain & Its Management,” which flagrantly misrepresented that scientific and/or medical studies demonstrated that chronic opioid therapy could improve patients’ “daily function, psychological health and overall health-related quality of life” (no such studies exist), mislabeled potential indicators of dangerous addictive behavior as “pseudoaddiction” that are mere “patient behaviors that may occur when pain is undertreated,” falsely claimed that “less than 1 percent of children treated with opioids become addicted,” and misstated the dangers associated with continually increasing dosages of PURDUE Opioids by claiming that such increased dosages are required to overcome tolerance and is “not necessarily indicative of addiction;” (ii) “Treatment Options: A Guide for People Living with Pain,” which impermissibly minimized the risks of chronic opioid therapy, and denigrated alternative treatment options like NSAIDs by falsely claiming that opioids have “no ceiling dose;” and (iii) “Exit Wounds,” a deceptive publication aimed at veterans that falsely states that the use of opioids increases functionality while grossly minimizing the risks of addiction.

99. PURDUE also acted in concert with FSMB in the creation of the “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain” in 1998 and 2004. In 2007, FSMB utilized the Guidelines to create a book titled *Responsible Opioid*

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<sup>49</sup> “Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Before the S. Committee On the Judiciary,” 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF). Strangely, no medical or scientific support exists for these statements. Moreover, APF’s board of directors included PURDUE KOL’s Russell Portenoy and Scott Fishman, as well as two other members who received consulting fees or had close connections with PURDUE (Lisa Weiss & Perry Fine).

*Prescribing*, which was also produced, disseminated, and popularized in conjunction with, and at the behest of, PURDUE. Overall, FSMB's publications represented (and continue to represent) the use of opioids in the treatment of chronic pain as "essential." The publications were widely distributed by the FSMB to state medical boards and practicing doctors. Although the 2012 revision no longer recommends chronic opioid therapy as a "first-line" treatment, it does continue to promote the concept of "pseudoaddiction" and suggests managing addiction risks via erroneous "screening tools."

100. With PURDUE's support, both the APS and the AAPM issued consensus guidelines in 1997 and 2009 endorsing chronic opioid therapy and minimizing the resulting risks of addiction. At the time that both sets of guidelines were issued, substantial portions of the reviewing and authoring members were in the putative service of PURDUE, including but not limited to Dr. David Haddox and Dr. Russell Portenoy. Although they have since been removed, the 2009 guidelines have been widely publicized, cited, and republished.

101. Cooperatively, PURDUE and AGS created and disseminated guidelines for the use of opioids for treating chronic pain in 2009 ("Pharmacological Management of Persistent Pain in Older Persons"). In particular, these guidelines advised, without citation to any authoritative source, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy" and that the risks of addiction resulting from opioid therapy "are exceedingly low in older patients with no current or past history of substance abuse."<sup>50</sup> Shockingly, the same document also suggested that "all patients with moderate to severe

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<sup>50</sup> See, e.g., "Pharmacological Management of Persistent Pain in Older Persons," 57 J. AM. GERIATRICS SOC'Y 1331, 1339, 1342 (2009).

pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy.”<sup>51</sup>

102. PURDUE utilized these third-party professional organizations in a variety of ways, including, but not limited to, publishing and popularizing so-called “guidelines” for the use of opioids for the treatment of chronic pain, publishing and popularizing articles, educational materials, and promotional materials that were supportive of PURDUE Opioids and/or chronic opioid therapy, supporting and publicizing the work and viewpoints of paid PURDUE KOLs, and other material support and marketing aimed at buttressing the illusory legitimacy of PURDUE Opioids and chronic opioid therapy.

103. Despite Defendants duty to truthfully represent the nature and efficacy of its drugs, these misrepresentations were made purely in service of the pursuit of profit. As a mere snapshot of the lucrative nature of Defendants’ activities reveals, PURDUE’s national annual sales of OxyContin in 2006 were approximately \$800 million. Thereafter, and since 2009, PURDUE’s nationwide sales of OxyContin has increased substantially and fluctuated between approximately \$2.5 billion and \$3 billion, every year.

104. Ultimately and as a direct result of these unscrupulous practices, in May 2007 PURDUE was forced to enter into a Consent Judgment with the Pennsylvania Office of Attorney General (as well as 26 other state jurisdictions) to avoid liability under the Commonwealth’s consumer protection law for its marketing of OxyContin, which required it to pay \$19.5 million and agree to a long list of restrictions on future marketing behavior.<sup>52</sup>

105. Although the consent judgment eventually expired in May 2017, the restrictions required that PURUDE do the following in the marketing of OxyContin: (i)

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<sup>51</sup> *Id.*

<sup>52</sup> *See, e.g., “Consent Judgment,” Commonwealth of Pennsylvania, et al. v. Purdue Pharma, Inc., et al., 238 M.D. 2007, (Pa. Commw. May 8, 2007).*

refrain from “any written or oral claim that is false, misleading or deceptive;” (ii) refrain from marketing or promotion that is “directly or indirectly inconsistent” with the FDA’s instructions regarding usage; (iii) include “fair balance” statements “regarding OxyContin’s potential for abuse, addiction, or physical dependence;” (iv) refrain from “misrepresentations with respect to OxyContin’s potential for abuse, addiction, or physical dependence;” (v) require that all recipients of “any educational grant, research grant, or other similar Remuneration relating to OxyContin” openly and conspicuously disclose their affiliation; (vi) refrain from misrepresenting “the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence;” (vii) refrain from sponsoring educational events promoting off-label uses of OxyContin; (viii) institute an “OxyContin Abuse and Diversion Detection Program” with regard to PURDUE’s employees; (ix) include “educational information related to detecting and prevent abuse and diversion of opioid analgesics” in all non-branded advertisements; and (x) to overall provide “only information that is truthful, balanced, accurately communicated” and which does not “minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin.”<sup>53</sup>

106. Upon information and belief, PURDUE’s conduct continued despite the existence of this Consent Judgment, up to and continuing after the filing of this civil action.

### iii. ABBOTT:

107. ABBOTT joined forces with Defendant PURDUE in 1996 through a co-promotion agreement. ABBOTT had a significant sales force already working in hospitals around the country and maintained ongoing relationships with doctors and pain treatment teams. Through the co-promotion agreement, ABBOTT devoted 300 sales representatives to OxyContin sales, which matched the sales force established by PURDUE.

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<sup>53</sup> *Id.* at ¶¶ 2-24.

108. ABBOTT actively marketed OxyContin from 1996 through 2002 and then continued to participate with PURDUE through 2006. With ABBOTT'S help, sales of OxyContin went from \$49 million in the first full year on the market to \$1.6 billion in 2002. Over the life of the agreement, Abbott was paid hundreds of millions of dollars.

109. ABBOTT heavily incentivized its sales force to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers. Top performers were given fanciful titles such as "Wizard of OxyContin" and "Supreme Sovereign of Pain Management." The head of pain care sales, Jerry Eichhorn, was known as the "King of Pain" and signed memos as simply "King."

110. In an internal memo, ABBOTT sales staff were instructed that if a doctor was concerned about the euphoria a patient experienced on the shorter-acting painkiller Vicodin, they should tell the physician "OxyContin has fewer such effects." Yet another memo told sales representatives to highlight the "less abuse/addiction potential" of OxyContin which could be taken just twice a day because of the time-release design. Representatives of ABBOTT were trained to only discuss potential abuse issues if a doctor brought it up and to inform them that "street users" were abusing the drug, and not "true pain patients."

111. Upon information and belief, ABBOTT utilized many of the same techniques as PURDUE with direct-to-physician marketing including food, gifts, and influence peddling, techniques that netted ABBOTT a huge portion of the profits from Purdue Opioid sales. Overall, the sales forces of PURDUE and ABBOTT worked in tandem, holding regular joint strategy sessions, alternating meeting locations between ABBOTT's headquarters and PURDUE's headquarters.

iv. **JOHNSON & JOHNSON:**

112. Similar to the efforts described above, JOHNSON & JOHNSON engaged in deceptive marketing efforts that impermissibly minimized the risks of addiction, overdose, dependence, and death, while simultaneously (and egregiously) overstating the benefits of chronic opioid therapy. Upon information and belief, JOHNSON & JOHNSON spent more than \$90 million on such efforts in 2011, alone.

113. As part of these marketing efforts, JOHNSON & JOHNSON maintained (and currently maintains) the website Prescribe Responsibly, which purports to provide information from “outside experts” provided “for the information of healthcare professionals in the United States only.”<sup>54</sup>

114. In a section titled “Use of Opioid Analgesics in Pain Management,” this website offers numerous statements that fly in the face of established medical science, including: (i) opioids have been utilized to treat chronic pain “for thousands of years;” (ii) opioids “have no true ‘ceiling dose’ for analgesia and do not cause direct organ damage;” (iii) failing to list “death” as a potential side effect of the use of opioid analgesics; (iv) dismissing concerns expressed by practitioners by stating that opioids “are often the only suite agent to control significant” chronic pain; (v) warning that the most severe potential adverse reaction is “the inadequate treatment of pain;” (vi) dismissing concerns about “excessive use of opioid analgesics” leading to a state of hyperalgesia by claiming that “lack of sufficient pain control may itself promote a state of hyperalgesia in the form of persistent pain;” (vii) dismissing concerns about the potential for addiction resulting from the use of opioids as “overestimated” and claiming that “true addiction occurs only in a small percentage of

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<sup>54</sup> JOHNSON & JOHNSON, “Prescribe Responsibly,” (July 2, 2015), available at <https://goo.gl/cGHgWG> (last accessed February 28, 2018).



patients with chronic pain who receive chronic opioid analgesics”; and (viii) concluding that “no agents have fully replaced opioid analgesics for the treatment of moderate to severe pain.”<sup>55</sup> These averments flagrantly misrepresent that opioids are considered standard in the treatment of so-called “chronic pain,” drastically understates the underlying risks of utilizing opioids (even in the short-term), while encouraging physicians to prescribe opioids freely and aggressively. Overall, JOHNSON & JOHNSON are utilizing the legitimate pain of its customers as a form of improper commercial coercion.

115. JOHNSON & JOHNSON also utilizes this website to advocate dangerously misinformative concepts such as “pseudoaddiction”<sup>56</sup> and “pseudotolerance”<sup>57</sup> that are intended to misrepresent and minimize the serious risks posed by the use of opioids. PrescribeResponsibly also draws an unsupported and outrageous distinction between addiction and physical dependence:

Physical dependence with long-term use of opioids should be expected. It is important to note that physical dependence is not the same as addiction. Physical dependence is a state of physiological adaptation manifested by a withdrawal syndrome produced by abrupt discontinuation of a medication . . . . Addiction is characterized by continued use of a drug despite detrimental effects and self-harm, impaired control over the use of a drug.

This distinction egregiously invites treating physicians to ignore the emergent signs of addiction as a mere hallmark of utilizing opioids in the long-term, as opposed to indications of a serious addiction-related condition.

<sup>55</sup> See, e.g., JOHNSON & JOHNSON, “Use of Opioid Analgesics in Pain Management,” (July 2, 2015), available at <https://goo.gl/ZTA9bR> (last accessed on February 28, 2018).

<sup>56</sup> See, e.g., JOHNSON & JOHNSON, “Before Prescribing Opioids,” (July 2, 2015), available at <https://goo.gl/EqkRvY> (last accessed on February 28, 2018) (“Pseudoaddiction is a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.”).

<sup>57</sup> *Id.* (“Pseudotolerance is the need to increase medication such as opioids for pain when other factor(s) are present such as disease progression, new disease, increased physical activity, lack of compliance, change in medication, drug interaction, addiction, and/or deviant behavior.”).

116. Similar representations appear in a section titled “Before Prescribing Opioids,” which advances circular and deeply misrepresentative theories concerning addiction and tolerance to opioids, arguing that “[c]onfusion between physical dependence and addiction may contribute to the undertreatment of chronic pain.” These representations include: (i) “[p]hysical dependence is a natural, expected neuroadaptive response that can occur with opioids;” (ii) “[t]olerance is also a natural, expected physiologic response” which is “neither good nor bad;” (iii) claiming that “[o]ne can treat acute pain in the face of an active addiction” with the use of opioids; (iv) arguing that the “stress” resulting from inadequately treated chronic pain is “[o]ne of the most common reasons for relapse of patients with addiction;” and (v) generally espousing that addiction concerns in the context of using opioids to treat chronic pain is something that can be eliminated through mere administrative measures.

117. The import of these representations is two-fold: (i) it seeks to draw non-existent distinctions between the addiction-related behaviors discussed above so as to assuage physician’s fears (and, thereby, encourage the same physicians to prescribe ever-increasing amounts of opioids to their patients); and (ii) suggest that addiction-related behaviors are simply the result of undertreated chronic pain (and, thereby, encourage the same physicians to prescribe ever-increasing amounts of opioids to their patients). JOHNSON & JOHNSON undertook these misrepresentations, despite knowledge of the very serious dangers related to addiction posed by chronic opioid therapy.

118. Upon information and belief, JOHNSON & JOHNSON also engaged in direct misleading marketing representations through its sales representatives, including spoken representations, the distribution and publication of promotional and educational materials, and telephone solicitations. Upon information and belief, JOHNSON &

JOHNSON instructed its sale representatives (directly and through training/administrative materials) to do the following: (ii) to trivialize and minimize the risks of addiction and withdrawal symptoms posed by the use of J&J Opioids; (iii) to claim that J&J Opioids had an exceedingly low incidence of withdrawal symptoms and that most patients who ceased utilizing J&J Opioids; (iv) to overemphasize the risks posed by pharmaceutical competitors with opioids (*e.g.*, NSAIDs); and (v) to claim that J&J Opioids can improve patients' quality of life and functionality. JOHNSON & JOHNSON instructed its sales representatives as above despite direct knowledge regarding the prolific problems regarding addiction, the dangers and risks posed by chronic opioid therapy, and the lack of a proper foundation in medical science.

119. Upon information and belief, JOHNSON & JOHNSON also maintained (and currently maintains) a Speakers Bureau and cultivated KOLs to help spread its deceptive message. The exact extent of these activities is presently unknown to Plaintiff, but is uniquely known to JOHNSON & JOHNSON.

120. Lastly, JOHNSON & JOHNSON also cooperated with various Front Groups in the creation and dissemination of additional misleading materials and information regarding J&J Opioids and chronic opioid therapy, in general. These activities included, but were not limited to: (i) collaborating with and exercising control over the AAPM and the AGS to create and disseminate a pamphlet titled "Finding Relief: Pain Management for Older Adults;"<sup>58</sup> (ii) collaborating with and exercising control over AGS in the production

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<sup>58</sup> In relevant part, this pamphlet makes a number of erroneous and troubling claims regarding chronic opioid therapy, including the following: (i) "opioids are rarely addictive when used properly for the management of chronic pain;" (ii) "opioids may make it easier for people to live normally;" (iii) rejecting the notion that "[o]pioid doses have to get bigger over time because the body gets used to them" by claiming that "you will probably remain on the same dose or need only small increases over time;" (iv) failing to advise of the serious risks posed by chronic opioid therapy, and representing those risks as merely "upset stomach or sleepiness;" and (v) claiming that "opioid medications make it possible for people with chronic pain to 'return to normal.'"

and dissemination of an aforementioned set of guidelines titled “Pharmacological Management of Persistent Pain in Older Persons;” (iii) collaborating and exercising control over APF, AAPM, and the American Society of Pain Management Nursing (“ASPMN”) in the creation and maintenance of a website titled Let’s Talk Pain that explicitly promoted the use of J&J Opioids and chronic opioid therapy;<sup>59</sup> and (iv) collaborating and exercising control over the APF in the publication of “Exit Wounds,” a publication that extolled the alleged virtues of chronic opioid therapy to veterans.<sup>60</sup>

121. Upon information and belief, JOHNSON & JOHNSON also sought to influence physicians through the creation and support of CMEs designed to misrepresent the efficacy of J&J Opioids and chronic opioid therapy and to play down the associated risks of such therapeutic treatments.

v. **ALLEGATIONS AS TO REMAINING DEFENDANTS:**

122. Upon information and belief, the remaining DEFENDANTS (*e.g.*, ABBVIE, DEPOMED, PERNIX, SHIONOGI, WEST-WARD, and ZOGENIX) have all acted similarly and in conformance with the course of conducts described above at length in promoting and distributing their respective products.<sup>61</sup>

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*See, e.g.*, AAPM, *et al.*, “Finding Relief: Pain Management for Older Adults” (2009), at 17. All of these claims are demonstrably false, and fly in the face of medical science and evidence-based medicine. Overall, this pamphlet also portrays opioids as a “cure-all” that is simultaneously the most-effective and least-dangerous option for the treatment of chronic pain (even though the opposite is true in both respects).

<sup>59</sup> Similarly, while it was still live, was intended to emphasize the illusory efficacy of chronic opioid therapy, and attempt to market J&J Opioids. The content on this website also minimized the risks of addiction (“Understanding Addiction”) by claiming that signs of “physical dependence” are not indications of addiction-related behavior and utilizing terms like “pseudoaddiction” to play down the seriousness of these concerns (and, thereby, encourage the wider use of J&J Opioids and chronic opioid therapy).

<sup>60</sup> Upon information and belief, Plaintiff avers that this pamphlet explicitly extols and inflates the potential benefits of chronic opioid therapy. In concert with JOHNSON & JOHNSON, APF cause this pamphlet to be distributed to organizations that support veterans recovering from battlefield injuries sustained in military service to the United States of America.

<sup>61</sup> *See, e.g., supra* at ¶ 68.

C. The U.S. Senate Has Identified and Quantified Collusive and Collaborative Behavior Between DEFENDANTS and Various Front Groups and Associated Individuals

123. On February 12, 2018, the ranking minority member of the U.S. Senate Homeland Security and Governmental Affairs Committee (Senator Claire McCaskill (D-MO)) released a report titled “Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups.”<sup>62</sup> Based in part upon responses to requests for information submitted by PURDUE, JOHNSON & JOHNSON, and DEPOMED<sup>63</sup> (as well as other information gathered regarding ENDO and TEVA) this report concluded that a mere sample of opioid manufacturers paid “nearly \$9 million in payments” to “14 outside groups working on chronic pain and other opioid-related issues between 2012 and 2017.”<sup>64</sup>

124. As discussed above in the individual sections, these 14 organizations include (but are not limited to): (i) the Academy of Integrative Pain Management; (ii) the American Academy of Pain Medicine (“AAPM”); (iii) the ACS Cancer Action Network; (iv) the American Chronic Pain Association; (v) the American Geriatrics Society (“AGS”); (vi) the American Pain Foundation (“APF”); (vii) the American Pain Society (“APS”); (viii) American Society of Pain Educators; (ix) American Society of Pain Management Nursing; (x) the Center for Practical Bioethics; (xi) the U.S. Pain Foundation; and (xii) the Washington Legal Foundation.<sup>65</sup>

125. The report suggests that this funding was directly tied to the fortunes and ownership of various opioid-based pharmaceuticals fluctuated across the chronology. For

<sup>62</sup> See, generally, HSGAC Report (identifying payments of \$8,856,339.13 to Front Groups over five-year period).

<sup>63</sup> In relevant part, DEPOMED reported contributing some \$1,071,116.95 to various Front Groups. *Id.* at 4.S

<sup>64</sup> *Id.* at 1.

<sup>65</sup> *Id.* at 4.

example, JOHNSON & JOHNSON's payments dropped from \$465,152.85 between 2012-14 to \$0 from 2015-17 following JOHNSON & JOHNSON's sale of the rights to Nucynta to DEPOMED. Conversely, DEPOMED's payments to these Front Groups "more than tripled" following its acquisition of Nucynta, paying some \$318,257.47 in 2016.<sup>66</sup>

126. In addition to support given directly to these Front Groups, DEFENDANTS also provided millions of dollars to individuals associated with these entities during this same time period, including: (i) President of the AAPM, Dr. Steven Stanos, who received over \$90,000 in payments between 2013-16; (ii) various AAPM board members, who received more than \$200,000 over a similar time period; (iii) ten members of the American Chronic Pain Association Advisory Board received more than \$140,000 (including from ENDO, PURDUE, TEVA, and DEPOMED); (iv) National Pain Foundation Chairman and founder Dr. Daniel Bennett, who received more than \$950,000 in payments; (v) more than \$7.9 million in "general payments" to at least half of the members of the National Pain Foundation Clinical and Scientific Advisory Council; and (vi) more than \$8 million in payments to "all individuals" affiliated with the National Pain Foundation.<sup>67</sup>

127. Overall, the report concluded there was a substantial basis to conclude that opioid manufacturers (including DEFENDANTS) were appropriating the platforms of these nominatively "neutral" advocacy groups for their own pecuniary benefit:

Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interest of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws direct at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and

<sup>66</sup> *Id.* at 5.

<sup>67</sup> *Id.* at 10-11.

Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain—the first national standards for prescription opioids and a key federal response to the ongoing epidemic.

\* \* \*

The fact that these manufacturers provided millions of dollars to the groups described [above] suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.<sup>68</sup>

128. While the true and entire extent of DEFENDANTS' collusive and misrepresentative conspiracy with the Front Groups remains unknown, research conducted by the Associated Press and the Center for Public Integrity indicates that opioid manufacturers (including DEFENDANTS) "spent more than \$880 million nationwide on lobbying and campaign contributions from 2006 through 2015—more than 200 times what those advocating for stricter [opioid] policies spent."<sup>69</sup>

129. Furthermore, the report concludes with this observation regarding the unknown amounts spent by DEFENDANTS prior to 2012:

[P]ayments between 2012 and 2017 may not fully reflect historical funding activities by manufacturers, given that several of the most prominent advocates in this space historically—the American Pain Foundation, for example—no longer operate. The fact that opioid prescribing, as measured in morphine milligram equivalents (MME) per capita, peaked between 2010 and 2012 before declining from 2012 to 2015 may also suggest more robust financing of advocacy groups in the pre-2012 period.<sup>70</sup>

130. These Front Groups—and the individuals associated with their activities—are non-party co-conspirators to the fraud and collusion outlined in this Complaint.

<sup>68</sup> *Id.* at 1; 14 ("[A] major concern is that opposition to regulatory, payment, or clinical policies to reduce opioid use may originate from groups that stand to lose financially if opioids sales decline.").

<sup>69</sup> *Id.* at 15 (quoting Liz Essley White, Geoff Mulvihill, and Ben Wieder, "Politics of pain: Drugmakers fought state opioid limits amid crisis," CTR. FOR PUB. INTEGRITY, (December 15, 2016), *available at* <https://goo.gl/zDB3oa>).

<sup>70</sup> *Id.* at 15.

**D. Other Allegations as to DEFENDANTS:**

131. At all times relevant hereto, DEFENDANTS also took steps to avoid detection of and to fraudulently conceal their deceptive marketing and conspiratorial behavior. DEFENDANTS disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through various third parties, KOLs, and Front Groups. DEFENDANTS purposefully hid behind these individuals and entities to avoid regulatory scrutiny and to prevent doctors and the public from discounting its messages.

132. In addition to hiding their own roles in generating the deceptive content, DEFENDANTS manipulated their promotional materials and the scientific literature to make it appear that the DEFENDANTS' deceptive message was accurate, truthful, and supported by substantial scientific evidence. DEFENDANTS distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The true lack of support for DEFENDANTS' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by Plaintiff.

133. While the opioid epidemic was raging, DEFENDANTS intentionally concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that Plaintiff now asserts. Plaintiff was not alerted to the existence and scope of DEFENDANTS' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through its public statements, marketing, and advertising, DEFENDANTS' deceptions deprived Plaintiff of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.



134. As a consequence of DEFENDANTS' collusion and deceptive marketing, the number of opioid-related overdoses and opioid-related addiction/dependence cases requiring medical intervention amongst the FUND's covered individuals has increased exponentially. In particular, treatment of these recognized, direct, and quantifiable medical results of DEFENDANTS' illegal behavior has required: (i) the prolific prescription and use of medications containing the drug naloxone (*e.g.*, Suboxone, Narcan, *etc.*) which reverses the effects of opioids and can save individuals from otherwise-fatal overdoses of opioids; and (ii) various other expenditures by the FUND regarding addiction-related treatments, including but not limited to in-patient and out-patient treatments (*e.g.*, rehabilitation, therapy, counseling), direct medical interventions, and hospital visits.

135. At all times relevant hereto, Plaintiff hereby avers that DEFENDANTS' conduct described above (as well as the conduct of DEFENDANTS' employees, agents, KOLs, Front Groups, and any other co-conspirators) was directed at and/or targeted the FUND and its beneficiaries, as well as at doctors/prescribers, healthcare facilities, patients, and commercial markets located in the Commonwealth of Pennsylvania, generally, and Philadelphia City and County, specifically.

136. Upon information and belief, Plaintiff avers that DEFENDANTS' course of conduct described above stretches across decades and continues up to the date of the filing of this Complaint.

### **COUNT I**

#### **INSURANCE FRAUD (CIVIL)**

137. Plaintiff incorporates herein by reference all other paragraphs of this Complaint as if fully set forth herein at length.

138. Plaintiff's claim against DEFENDANTS for insurance fraud is brought pursuant to 18 Pa.C.S. § 4117(g), which provides a civil cause of action to insurers that are damaged as a result of conduct declared illegal under 18 Pa.C.S. §§ 4117(a)-(b).

139. Plaintiff is an "insurer" as defined by Section 4117(l). *See, e.g.*, 18 Pa.C.S. § 4117(l) (including, but not limited to, "an unincorporated association of underwriting members," "a fraternal benefits society," and/or "a self-insured health care entity").

140. DEFENDANTS are each considered a "person" under the meaning of Section 4117(a). *See, e.g.*, 18 Pa.C.S. § 4117(a).

141. DEFENDANTS' pattern and course of conduct described throughout this Complaint constitute serial violations of Section 4117(a)(2), which criminalizes the behavior of anyone who "[k]nowingly and with the intent to defraud any insurer or self-insured, [present] or [cause] to be presented to any insurer or self-insured any statement forming a part of, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim." 18 Pa.C.S. § 4117(a)(2).

142. DEFENDANTS' pattern and course of conduct described throughout this Complaint also constitute serial violations of Section 4117(a)(3), which criminalizes the behavior of anyone who "[k]nowingly and with the intent to defraud any insurer or self-insured, assists, abets, solicits or conspires with another to prepare or make any statement that is intended to be presented to any insurer or self-insured in connection with, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim, including information which documents or supports an amount claimed in excess of the actual loss sustained by the claimant." 18 Pa.C.S. § 4117(a)(3).

143. DEFENDANTS' pattern and course of conduct described throughout this Complaint also constitute serial violations of Section 4117(a)(5), which criminalizes the behavior of anyone who "[k]nowingly benefits, directly or indirectly, from the proceeds derived from a violation of this section due to the assistance, conspiracy or urging of any person." 18 Pa.C.S. § 4117(a)(5).

144. Specifically, DEFENDANTS and each of them together with their named and unnamed co-conspirator KOLS, associated Front Groups, employees, agents, servants, officers, directors, and other representatives, misrepresented, deceived, concealed, omitted, and/or failed to inform Plaintiff FUND and its participants, retirees, and their dependents, and the doctors prescribing OPIOIDS that the use of OPIOIDS was neither safe nor efficacious in the treatment of chronic pain or other long-term medical conditions.

145. To the contrary, DEFENDANTS affirmatively did the opposite by convincing Plaintiff and the FUND's participants, retirees, and their dependents and the prescribing doctors that the use and ever regular or continued use was safe and effective for the treatment of chronic pain and other long term medical conditions. DEFENDANTS' impermissible behavior is well-described throughout this Complaint, and includes direct and indirect (*i.e.*, carried out by DEFENDANTS' agents, employees, representatives, paid speakers, servants, and/or KOLs) actions: (a) concealing, deceiving, obfuscating, or otherwise misrepresenting the results of definitive medical studies and persuasive empirical research demonstrating the dangers associated with chronic opioid therapy and OPIOIDS; (b) deliberately misrepresenting and/or deceptively describing the efficacy of OPIOIDS at managing chronic pain and other long-term medical conditions; (c) publishing or causing to be published various materials containing false or deceptive information upon which physicians, Plaintiff and the FUND's participants, retirees, and their dependents relied upon

in choosing to prescribe, pay for, or take OPIOIDS when safer, more effective, and less expensive treatments were available for the management of chronic pain and other long-term medical conditions; and (d) otherwise creating confusion and uncertainty regarding the safe, recommended, and medically sound therapeutic uses of OPIOIDS.

146. In so doing, DEFENDANTS deprived the FUND and its participants, retirees, and their dependents, and the prescribing doctors treating those same individuals of information that was relevant, material, and vital to the decision of whether or not to prescribe OPIOIDS to Plaintiff's beneficiaries under their health insurance plans.

147. These serial misrepresentations of material facts regarding the efficacy and safety of OPIOIDS perpetrated by DEFENDANTS ultimately caused (and were intended to cause) the FUND and its participants, retirees, and their dependents to either purchase—or seek reimbursements for the purchase of—OPIOIDS marketed by DEFENDANTS for purposes and/or treatments that were inconsistent with the medically and/or scientifically approved uses of such drugs (*i.e.*, chronic opioid therapy).

148. DEFENDANTS' misrepresentations also caused a dramatic increase in the number of opioid-related overdoses and opioid-related addiction/dependence cases requiring medical intervention amongst the FUND's covered individuals. Plaintiff is also seeking compensation for the treatment of these recognized, direct, and quantifiable medical results of DEFENDANTS' illegal behavior, including, but not limited to: (i) the prolific prescription and use of medications containing the drug naloxone (*e.g.*, Suboxone, Narcan, *etc.*) which reverses the effects of opioids and can save individuals from otherwise-fatal overdoses of opioids; and (ii) various other expenditures by the FUND regarding addiction-related treatments, including but not limited to in-patient and out-patient treatments (*e.g.*, rehabilitation, therapy, counseling), direct medical interventions, and hospital visits.

149. DEFENDANTS' schemes discussed throughout this Complaint were calculated to ensure that the FUND would be wrongfully induced to cover and/or reimburse for these expenses related to the purchase and use of OPIOIDS, thereby enriching DEFENDANTS at the expense of Plaintiff.

150. DEFENDANTS' were and are aware that Plaintiff depended upon the accuracy and reasonableness of a patients' course of treatment when deciding whether to approve and pay for related expenses, up to and including the cost of OPIOIDS.

151. The above-described pattern of insurance fraud amounted to a common course of conducted intended to deceive Plaintiff. Each fraudulent act was related, had similar purposes, involved similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff. DEFENDANTS' fraudulent activities were and are part of its regular way of conducting its ongoing business, and constitute a present and continuing threat to Plaintiff.

152. By reason of the foregoing and as a proximate cause of said pattern of fraudulent activity and acts committed in furtherance thereof, Plaintiff has suffered injury and has been damaged as alleged herein.

153. Each of the fraudulent acts detailed in this Complaint constitutes "insurance fraud" within the meaning of 18 Pa.C.S. §§ 4117(a)(2)-(3), (5). Collectively, these violations constitute a pattern of fraudulent behavior within the meaning of 18 Pa.C.S. § 4117(g).

**WHEREFORE**, Plaintiff respectfully requests that this Honorable Court enter judgment against DEFENDANTS on Count I and award Plaintiff actual and statutory damages for each instance of fraudulent behavior that resulted in a claim (*i.e.*, the payment by Plaintiff for each claim presented for each and every one of the OPIOIDS they manufactured; and each instance in which DEFENDANTS misrepresented and/or

deceptively represented the efficacy and risks associated with, or otherwise obfuscated the truth regarding the therapeutic uses of OPIOIDS and chronic opioid therapy), consequential damages (*i.e.*, each and every instance when Plaintiff paid for the treatment of an opioid-related overdose or opioid-related addiction treatment, including prescriptions for naloxone-based medications, hospital visits, therapy, rehabilitation, and other medical interventions), treble damages, together with interest, costs of investigation, costs of litigation, reasonable attorneys' fees, and expenses in an amount in excess of \$50,000 and such other relief as the Court deems appropriate.

## **COUNT II**

### **DISGORGEMENT OF PROFITS**

154. Plaintiff incorporates herein by reference all other paragraphs of this Complaint as if fully set forth herein at length.

155. DEFENDANTS are the manufacturer, seller, and/or supplier of OPIOIDS. Through the wrongful and deceptive conduct described at length above, DEFENDANTS have reaped substantial profits from the sale of OPIOIDS. Yet, DEFENDANTS' profits would have been significantly and substantially reduced but for their wrongful, deceptive and unlawful conduct.

156. Accordingly, and as described in this Complaint, DEFENDANTS have been unjustly enriched by their unlawful, deceptive and wrongful conduct. DEFENDANTS should not be allowed to retain the proceeds from the benefits conferred upon them by Plaintiff (*i.e.*, the purchase and/or reimbursement for purchase of OPIOIDS). DEFENDANTS knew that Plaintiff paid for, or reimbursed for purchases of, OPIOIDS that were not medically necessary, generally ineffective, and fundamentally unsafe. Moreover, the use of OPIOIDS in the treatment of chronic pain and/or other long-term

medical conditions offered no greater benefits than those offered by less expensive medications and treatment options.

157. It is unjust and inequitable to permit DEFENDANTS to enrich themselves at the expense of Plaintiff by retaining the benefit of the various expenditures for OPIOID prescriptions that were not medically necessary, effective, or, alternatively, no more efficacious than less expensive, substantially safer medical alternatives, or that were simply the result of DEFENDANTS' own deceptive marketing strategies. Accordingly, DEFENDANTS must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution and/or rescission to Plaintiff.

**WHEREFORE**, Plaintiff respectfully requests that this Honorable Court enter judgment in their favor and against DEFENDANTS for compensatory and actual damages related to their purchases and reimbursement for purchases of OPIOIDS, in an amount in excess of \$50,000, together with interest, costs of litigation, attorneys' fees, and any other such relief as this Honorable Court may deem just and proper.

### **COUNT III**

#### **BREACH OF IMPLIED WARRANTIES**

158. Plaintiff incorporates herein by reference all other paragraphs of this Complaint as if fully set forth herein at length.

159. DEFENDANTS, in the manufacture, marketing, and sale of OPIOIDS impliedly warranted to Plaintiff that OPIOIDS were appropriate for their particular and understood ordinary purpose as presented by DEFENDANTS: namely, the treatment of chronic pain and/or other long-term medical conditions.

160. DEFENDANTS and its agents, employees, servants, paid speakers, KOLs and/or other representatives knew or should have known that OPIOIDS were ineffective

(and inherently dangerous) treatment options in the management of chronic pain and other long-term medical conditions.

161. Plaintiff reasonably relied upon the skill and judgment of DEFENDANTS and its agents, employees, servants, paid speakers, KOLs and/or other representatives as to whether OPIOIDS were of merchantable quality, safe, and fit for their intended uses as described by DEFENDANTS.

162. Pursuant to the Pennsylvania Commercial Code,<sup>71</sup> there exists an implied warranty of merchantability for DEFENDANTS marketing and sale of OPIOIDS. *See, e.g.,* 13 Pa.C.S. §§ 2314-15.

163. DEFENDANTS breached this implied warranty of merchantability by promoting, marketing, and selling OPIOIDS as being fit for the “ordinary purpose” ascribed by DEFENDANTS (*i.e.*, the treatment of chronic pain and/or other long-term medical conditions) when, in fact, OPIOIDS are inappropriate, dangerous, and unfit for that purpose.

**WHEREFORE**, Plaintiff respectfully requests that this Honorable Court enter judgment for them and against DEFENDANTS, for compensatory and consequential damages related to their purchases and reimbursements for purchases of OPIOIDS, in an amount in excess of \$50,000, together with interest, costs of litigation, attorneys’ fees, and all other such relief as this Honorable Court may deem just and proper.

#### **COUNT IV**

#### **CIVIL CONSPIRACY**

164. Plaintiff incorporates herein by reference all other paragraphs of this Complaint as if fully set forth herein at length.

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<sup>71</sup> 13 Pa.C.S. §§ 1101, *et seq.*



165. DEFENDANTS conspired amongst themselves and with various KOLs and Front Groups as described throughout this Complaint in order to commit unlawful acts, including the serial violations of the Pennsylvania Insurance Fraud Statute detailed at length above. In particular, DEFENDANTS and the various KOLs and Front Groups knowingly and voluntarily agreed to present or cause to be presented statements used in whole or in part, to support a claim for payment for OPIOIDS that contained false, incomplete and/or misleading information concerning the material facts regarding the uses, need for, and prescribing of OPIOIDS simply to promote the use of OPIOIDS for the treatment of chronic pain and other long-term medical conditions. To that end, DEFENDANTS cooperated amongst themselves, and enlisted various KOLs and Front Groups to produce and disseminate statements and materials in furtherance of this common strategy, despite knowledge of the misleading nature of these activities.

166. Together with and in collusion with Front Groups including the APF, NIPC, AGS, FSMB, APS, and AAPM, DEFENDANTS agreed to deceptively and misleadingly promote the benefits and superiority of chronic opioid therapy and OPIOIDS, while minimizing the associated risks. As part of these agreements, DEFENDANTS provided material, financial, and other forms of support to the Front Groups, which in turn used that support to more broadly disseminate the deceptive and misleading messaging regarding OPIOIDS and chronic opioid therapy. The publications, marketing materials, CMEs, programs, and substantive representations produced and publicized by these Front Groups are each products of a civil conspiracy, and each instance of collaboration between DEFENDANTS and the Front Groups is evidence of an overt act taken in furtherance of that conspiracy.

167. Together and in collusion with KOLs including David Haddox, Lynn R. Webster, Russell Portenoy, Kathleen Foley, Christine A. Miaskowski, Michael J. Brennan, Perry Fine, Scott Fishman, Lisa Weiss, and others unknown to Plaintiff but known to and identifiable to DEFENDANTS, DEFENDANTS agreed both overtly and tacitly among themselves and others, to deceptively and misleadingly promote the benefits and superiority of chronic opioid therapy and OPIOIDS, while minimizing the associated risks. As part of these agreements, DEFENDANTS provided material, financial, and other forms of support to the KOLs, who in turn used that support to more broadly disseminate the deceptive and misleading messaging regarding OPIOIDS and chronic opioid therapy. The publications, marketing materials, CMEs, programs, and substantive representations produced and publicized by these KOLs are each products of a civil conspiracy, and each instance of collaboration between DEFENDANTS and the KOLs is evidence of an overt act taken in furtherance of that conspiracy.

168. DEFENDANTS also mutually worked amongst themselves towards a shared common purpose, and explicitly cooperated with one another in the pursuit of that common purpose. Specifically, that purpose included: (i) the popularization and proliferation of “chronic opioid therapy,” and (ii) the increase of sales of OPIOIDS. DEFENDANTS explicitly cooperated in the sale of certain OPIOIDS, including but not limited to ABBOTT and PURDUE’s cooperation in the sales of OxyContin. Each such instance of collaboration between DEFENDANTS in pursuit of this common purpose is evidence of an overt act taken in furtherance of that conspiracy.

169. DEFENDANTS also explicitly cooperated in their support, control of, and direction of the Front Groups and KOLs discussed above. DEFENDANTS’ material support of the Front Groups and KOLs are products of a civil conspiracy, and each instance

of collaboration between DEFENDANTS in supporting the efforts of the Front Groups and KOLs is evidence of an overt act taken in furtherance of that conspiracy.

170. Each of the participants in this conspiracy were fully aware of the deceptive and misleading nature of the statements, research, and other materials that they utilized in promoting OPIOIDS. Nonetheless, DEFENDANTS and the Front Groups agreed to mislead and deceive Plaintiff regarding the risks, benefits, and alleged superiority of chronic opioid therapy and OPIOIDS, in exchange for increased pharmaceutical sales, financial contributions, reputational enhancements, and other pecuniary and professional benefits.

171. As outlined at length above, DEFENDANTS played an active role in determining the substance and format of the misleading and deceptive messaging issued by KOLs and Front Groups, including directly providing content, editing, and otherwise approving content produced by its co-conspirators. DEFENDANTS, KOLs, and Front Groups also collectively ensured that these materials were widely disseminated by cooperative distribution, material support and republication. The result was an unrelenting stream of misleading information regarding the risks, benefits, and alleged superiority of chronic opioid therapy and OPIOIDS.

172. Even if DEFENDANTS did not directly disseminate or control the content of all of these misleading and deceptive representations, they are liable for conspiring with the third parties that did so (*i.e.*, KOLs and Front Groups).

173. DEFENDANTS' conspiracy, and the consummation of that conspiracy via the overt acts described above, amongst themselves and with these third parties (*e.g.*, KOLs and Front Groups) were unlawful (criminal and civil) acts under the Pennsylvania Insurance Fraud Statute, 18 Pa.C.S. §4117.

174. Upon information and belief, Plaintiff avers that DEFENDANTS' conspiracy, and the actions consummating that conspiracy, were undertaken with malice.

175. As a result of DEFENDANTS' conspiracy and related unlawful acts, Plaintiff has been damaged and continues to be damaged by paying for the costs of or reimbursements for OPIOIDS for the treatment of chronic pain and/or other long-term medical conditions.

176. Because DEFENDANTS' conspiracy ultimately caused doctors and other health care providers to prescribe (and, consequently, Plaintiff to pay for) long-term treatments via OPIOIDS, DEFENDANTS caused and is responsible for those costs and claims. In addition, DEFENDANTS are both criminally and civilly liable for the insurance fraud they perpetrated upon Plaintiff and others arising out of and directly caused by their knowing and intentional conduct described above.

**WHEREFORE**, Plaintiff respectfully requests that this Honorable Court enter judgment for them and against DEFENDANTS, for direct and consequential damages related to their purchases and reimbursements for purchases of DEFENDANTS' Opioids, in an amount in excess of \$50,000, together with interest, costs of litigation, attorneys' fees, and all other such relief as this Honorable Court may deem just and proper.

**ANAPOL WEISS**

BY: /s/ DAVID S. SENOFF  
SOL H. WEISS, ESQUIRE  
DAVID S. SENOFF, ESQUIRE  
HILLARY B. WEINSTEIN, ESQUIRE  
CLAYTON P. FLAHERTY, ESQUIRE  
130 N. 18<sup>TH</sup> STREET, SUITE 1600  
PHILADELPHIA, PA 19103

**FRITZ & BIANCULLI, LLC**

BY: /s/ BRIAN E. FRTIZ  
BRIAN E. FRTIZ, ESQUIRE  
1515 MARKET STREET, SUITE 1801  
PHILADELPHIA, PA 19102

*ATTORNEYS FOR PLAINTIFF*

DATED: MAY 23, 2018.

VERIFICATION

I, Stephen E. Conley, do verify that the information contained in the foregoing Complaint is true and correct to the best of my knowledge, information and belief. I understand that false statements herein made are subject to the penalties of 18 Pa.C.S. §4904 relating to unsworn falsification to authorities.

Stephen E. Conley

DATED: 5/18/18

# **EXHIBIT C**

## IN THE CIRCUIT COURT OF CRITTENDEN COUNTY, ARKANSAS

STATE OF ARKANSAS, *ex rel.* SCOTT )  
 ELLINGTON, Second Judicial Circuit Prosecuting )  
 Attorney; COUNTY OF ARKANSAS, )  
 ARKANSAS; COUNTY OF ASHLEY, )  
 ARKANSAS; COUNTY OF BAXTER, )  
 ARKANSAS; COUNTY OF BENTON, )  
 ARKANSAS; COUNTY OF BOONE, )  
 ARKANSAS; COUNTY OF BRADLEY, )  
 ARKANSAS; COUNTY OF CALHOUN, )  
 ARKANSAS; COUNTY OF CHICOT, )  
 ARKANSAS; COUNTY OF CLARK, )  
 ARKANSAS; COUNTY OF CLAY, ARKANSAS; )  
 COUNTY OF CLEBURNE, ARKANSAS; )  
 COUNTY OF COLUMBIA, ARKANSAS; )  
 COUNTY OF CONWAY, ARKANSAS; )  
 COUNTY OF CRAIGHEAD, ARKANSAS; )  
 COUNTY OF CRAWFORD, ARKANSAS; )  
 COUNTY OF CROSS, ARKANSAS; COUNTY )  
 OF DALLAS, ARKANSAS; COUNTY OF )  
 DESHA, ARKANSAS; COUNTY OF )  
 FAULKNER, ARKANSAS; COUNTY OF )  
 FRANKLIN, ARKANSAS; COUNTY OF )  
 FULTON, ARKANSAS; COUNTY OF )  
 GARLAND, ARKANSAS; COUNTY OF GRANT, )  
 ARKANSAS; COUNTY OF GREENE, )  
 ARKANSAS; COUNTY OF HEMPSTEAD, )  
 ARKANSAS; COUNTY OF HOT SPRING, )  
 ARKANSAS; COUNTY OF HOWARD, )  
 ARKANSAS; COUNTY OF INDEPENDENCE, )  
 ARKANSAS; COUNTY OF IZARD, )  
 ARKANSAS; COUNTY OF JACKSON, )  
 ARKANSAS; COUNTY OF JOHNSON, )  
 ARKANSAS; COUNTY OF LAFAYETTE, )  
 ARKANSAS; COUNTY OF LAWRENCE, )  
 ARKANSAS; COUNTY OF LEE, ARKANSAS; )  
 COUNTY OF LINCOLN, ARKANSAS; )  
 COUNTY OF LITTLE RIVER, ARKANSAS; )  
 COUNTY OF LOGAN, ARKANSAS; COUNTY )  
 OF LONOKE, ARKANSAS; COUNTY OF )  
 MADISON, ARKANSAS; COUNTY OF )  
 MARION, ARKANSAS; COUNTY OF MILLER, )  
 ARKANSAS; COUNTY OF MISSISSIPPI, )  
 ARKANSAS; COUNTY OF MONROE, )  
 ARKANSAS; COUNTY OF MONTGOMERY, )  
 ARKANSAS; COUNTY OF OUACHITA, )

Case No.: CV-2018-268

JURY TRIAL DEMANDED

FILED  
 2018 APR -2 PM 3:52  
 TERRY HAWKINS  
 CIRCUIT COURT CLERK  
 CRITTENDEN COUNTY, AR



ARKANSAS; COUNTY OF PERRY, )  
ARKANSAS; COUNTY OF PHILLIPS, )  
ARKANSAS; COUNTY OF PIKE, ARKANSAS; )  
COUNTY OF POINSETT, ARKANSAS; )  
COUNTY OF POLK, ARKANSAS; COUNTY OF )  
POPE, ARKANSAS; COUNTY OF PRAIRIE, )  
ARKANSAS; COUNTY OF RANDOLPH, )  
ARKANSAS; COUNTY OF ST. FRANCIS, )  
ARKANSAS; COUNTY OF SALINE, )  
ARKANSAS; COUNTY OF SCOTT, )  
ARKANSAS; COUNTY OF SEARCY, )  
ARKANSAS; COUNTY OF SEBASTIAN, )  
ARKANSAS; COUNTY OF SEVIER, )  
ARKANSAS; COUNTY OF SHARP, )  
ARKANSAS; COUNTY OF STONE, )  
ARKANSAS; COUNTY OF UNION, )  
ARKANSAS; COUNTY OF VAN BUREN, )  
ARKANSAS; COUNTY OF WASHINGTON, )  
ARKANSAS; COUNTY OF WHITE, )  
ARKANSAS; COUNTY OF WOODRUFF, )  
ARKANSAS; COUNTY OF YELL, ARKANSAS; )  
COUNTY OF CARROLL, ARKANSAS; )  
COUNTY OF NEWTON, ARKANSAS; COUNTY )  
OF NEVADA, ARKANSAS; COUNTY OF )  
CLEVELAND, ARKANSAS; COUNTY OF )  
CRITTENDEN, ARKANSAS; COUNTY OF )  
PULASKI, ARKANSAS; COUNTY OF )  
JEFFERSON, ARKANSAS; CITY OF LITTLE )  
ROCK, ARKANSAS; CITY OF FORT SMITH, )  
ARKANSAS; CITY OF SPRINGDALE; )  
ARKANSAS; CITY OF JONESBORO, )  
ARKANSAS; CITY OF NORTH LITTLE ROCK; )  
ARKANSAS; CITY OF CONWAY, ARKANSAS; )  
CITY OF ROGERS, ARKANSAS; CITY OF PINE )  
BLUFF, ARKANSAS; CITY OF BENTONVILLE, )  
ARKANSAS; CITY OF HOT SPRINGS, )  
ARKANSAS; CITY OF BENTON, ARKANSAS; )  
CITY OF TEXARKANA, ARKANSAS; CITY OF )  
SHERWOOD, ARKANSAS; CITY OF )  
JACKSONVILLE, ARKANSAS; and CITY OF )  
MONTICELLO, ARKANSAS; )

Plaintiffs, )

v. )

PURDUE PHARMA, L.P.; PURDUE PHARMA, )  
INC.; THE PURDUE FREDERICK COMPANY; )  
CEPHALON, INC.; TEVA PHARMACEUTICAL )  
INDUSTRIES, LTD; TEVA )  
PHARMACEUTICALS USA, INC.; JANSSEN )  
PHARMACEUTICALS, INC.; ORTHO-MCNEIL- )  
JANSSEN PHARMACEUTICALS, INC.; )  
JOHNSON & JOHNSON; WATSON )  
LABORATORIES, INC.; ACTAVIS PHARMA, )  
INC.; WATSON PHARMA, INC.; ACTAVIS, )  
LLC; ENDO HEALTH SOLUTIONS, INC.; )  
ENDO PHARMACEUTICALS, INC.; VINTAGE )  
PHARMACEUTICALS, LLC; INSYS )  
THERAPEUTICS, INC.; MALLINCKRODT, PLC; )  
MALLINCKRODT PHARMACEUTICALS; )  
MYLAN PHARMACEUTICALS, INC.; SUN )  
PHARMACEUTICALS INDUSTRIES, INC.; )  
AUROBINDO PHARMA USA, INC.; AUROLIFE )  
PHARMA, LLC; LUPIN PHARMACEUTICALS; )  
INC.; COLLEGIUM PHARMACEUTICAL, INC.; )  
BIODELIVERY SCIENCES INTERNATIONAL, )  
INC.; SHIONOGI, INC.; ABBVIE, INC.; )  
ABBOTT LABORATORIES, INC.; PERNIX )  
THERAPEUTICS HOLDINGS, INC.; DAIICHI )  
SANKYO, INC.; FOREST LABORATORIES, )  
INC.; FOREST PHARMACEUTICALS, INC.; )  
MAYNE PHARMA, INC.; APOTEX, INC.; )  
WEST-WARD PHARMACEUTICALS CORP.; )  
GEMINI LABORATORIES, LLC; )  
POLY-PHARMACEUTICALS, INC.; AKORN, )  
INC.; VALEANT PHARMACEUTICALS )  
NORTH AMERICA, LLC; ECR )  
PHARMACEUTICALS, INC.; DEPOMED, INC.; )  
VALIDUS PHARMACEUTICALS, LLC; )  
EGALET CORPORATION; VERNALIS )  
THERAPEUTICS, INC.; UCB PHARMA, INC.; )  
XANODYNE PHARMACEUTICALS, INC.; )  
VERTICAL PHARMACEUTICALS, INC.; )  
SENTYNL THERAPEUTICS, INC.; RHODES )  
TECHNOLOGIES, INC.; RHODES )  
TECHNOLOGIES, L.P.; SANDOZ, INC.; )  
AMERISOURCEBERGEN DRUG )  
CORPORATION; CARDINAL HEALTH, INC.; )  
MCKESSON CORPORATION; LINDEN CARE, )  
LLC; KJ MEDICAL MANAGEMENT, LLC; )  
CJN PHARMACY SERVICES, LLC; PERRY )

COUNTY FOOD & DRUG, INC.; MAHMOOD )  
AHMAD, M.D.; UNITED PAIN CARE, LTD; )  
SHAWN MICHAEL BROOKS, M.D.; KRISTEN )  
HOLLAND; RICHARD DUANE JOHNS; and )  
CHRISTOPHER WATSON; )

Defendants. )

TABLE OF CONTENTS

|   |           |
|---|-----------|
| <b>I. INTRODUCTION.....</b>   | <b>1</b>  |
| A. Opioids devastate Arkansas public health and welfare.....  | 1         |
| B. The Opioid Epidemic emerges from a conspiracy of greed. ....   | 10        |
| <b>II. PARTIES.....</b>   | <b>14</b> |
| A. Plaintiffs.....  | 14        |
| B. Manufacturer Defendants.....   | 27        |
| C. Distributor Defendants.....  | 39        |
| D. Retail Defendants.....   | 39        |
| E. Physician Defendants.....  | 41        |
| <b>III. JURISDICTION.....</b>   | <b>42</b> |
| <b>IV. VENUE.....</b>   | <b>44</b> |
| <b>V. FACTUAL ALLEGATIONS.....</b>  | <b>44</b> |
| A. Manufacturer Defendants used multiple avenues to disseminate their false and<br>deceptive statements about opioids.....  | 45        |
| 1. Key Opinion Leaders ("KOLs").....  | 49        |
| 2. Front Groups.....  | 53        |
| B. The U.S. Senate Homeland Security and Governmental Affairs Committee<br>February 2018 Minority Staff Report recognizes collusive opioid promotion<br>between Manufacturer Defendants and Front Groups..... | 59        |
| C. Manufacturer Defendants' marketing scheme misrepresented the risks and benefits<br>of opioids. ....  | 61        |
| 1. Manufacturer Defendants falsely trivialized or failed to disclose the known<br>risks of long-term opioid use.....  | 61        |
| 2. Manufacturer Defendants grossly overstated the benefits of chronic opioid<br>therapy.....  | 71        |
| 3. Manufacturer Defendants also engaged in other unlawful, unfair, and<br>fraudulent misconduct. ....   | 74        |

|                   |   |            |
|-------------------|---|------------|
| D.                | Manufacturer Defendants targeted susceptible prescribers and vulnerable patient populations.....  | 75         |
| E.                | Although Manufacturer Defendants knew that their marketing of opioids was false and deceptive, they fraudulently concealed their misconduct.....                        | 76         |
| F.                | By increasing opioid prescriptions and use, Manufacturer Defendants' deceptive marketing scheme has fueled the Opioid Epidemic and devastated Arkansas communities..... | 78         |
| G.                | Distributor Defendants likewise breached their duties to Plaintiffs.....  | 82         |
| H.                | Distributor Defendants knew or should have known they were facilitating widespread opioid diversion.....  | 85         |
| I.                | Distributor Defendants' misconduct has injured and continues to injure Plaintiffs.....  | 88         |
| J.                | Insys, Linden Care, UPC, and Ahmad's Arkansas Scheme.....   | 91         |
| 1.                | The Fraudulent Scheme to Illegally Promote Fentanyl Spray.....  | 91         |
| K.                | Additional Arkansas Diversion Schemes Exposed by Operation Pilluted.....  | 101        |
| 1.                | The KJ Medical Clinic, Dr. Shawn Michael Brooks, Dr. Jerry Reifeiss, Bowman Curve, and Kristen Holland Opioid Diversion Scheme.....                                     | 101        |
| 2.                | The Perry County Food & Drug and Christopher Watson Opioid Diversion Scheme.....  | 102        |
| 3.                | The Dr. Richard Duane Johns Opioid Diversion Scheme.....  | 103        |
| L.                | The Arkansas opioid diversion exposed by federal and state investigation is only the tip of the iceberg.....  | 104        |
| <b>VI.</b>        | <b>CAUSES OF ACTION.....</b>  | <b>105</b> |
| <b>COUNT I:</b>   | <b>Negligence/Gross Negligence.....</b>   | <b>105</b> |
| <b>COUNT II:</b>  | <b>Common Law Public Nuisance.....</b>  | <b>111</b> |
| <b>COUNT III:</b> | <b>Violations of the Uniform Narcotic Drug Act.....</b>   | <b>114</b> |
| <b>COUNT IV:</b>  | <b>Accomplice to Violations of the Uniform Narcotic Drug Act.....</b>   | <b>116</b> |
| <b>COUNT V:</b>   | <b>Civil Conspiracy to Violate the Uniform Narcotic Drug Act.....</b>   | <b>118</b> |
| <b>COUNT VI:</b>  | <b>Violations of the Arkansas Controlled Substances Act.....</b>  | <b>120</b> |

|  |     |
|--|-----|
| COUNT VII: Accomplice to Violations of the Arkansas Controlled Substances Act .....  | 121 |
| COUNT VIII: Civil Conspiracy to Violate the Arkansas Controlled Substances Act ..... | 123 |
| COUNT IX: Violations of the Arkansas Drug Dealer Liability Act .....                 | 125 |
| VII. JOINT AND SEVERAL LIABILITY .....   | 128 |
| PRAYER FOR RELIEF .....  | 128 |

## SECOND AMENDED COMPLAINT

Plaintiffs, the State of Arkansas; Counties of the State of Arkansas (hereinafter "the Counties" or by their respective county names), and Cities of the State of Arkansas (hereinafter "the Cities" or by their respective city names) (hereinafter "Plaintiffs" or identified by their respective names), allege as follows:

### I. INTRODUCTION

#### A. Opioids devastate Arkansas public health and welfare.

1. Drug poisoning is the leading cause of injury and death in the United States, outnumbering those caused by firearms, car crashes, suicide, and homicide.<sup>1</sup> Controlled prescription drugs, specifically opioid analgesics (painkillers), have been linked to the largest number of overdose deaths of any illicit drug class, outnumbering cocaine and heroin combined.<sup>2</sup> Since 1999, the number of overdose deaths involving opioids has quadrupled.<sup>3</sup> By 2015, opioids were responsible for 63% of all drug-overdose deaths,<sup>4</sup> and that number climbed to 66% in 2016.<sup>5</sup> The Centers for Disease Control and Prevention ("CDC") has stated that "[w]e now know that overdoses from prescription opioids are a driving factor in the 15-year increase in opioid overdose deaths,"<sup>6</sup> and that opioids are, in fact, the main driver of drug overdose deaths.<sup>7</sup>

<sup>1</sup> Drug Enforcement Administration, *2017 National Drug Threat Assessment*, at v (Oct. 2017), available at [https://www.dea.gov/docs/DIR-040-17\\_2017-NDTA.pdf](https://www.dea.gov/docs/DIR-040-17_2017-NDTA.pdf) (last visited Feb. 9, 2018).

<sup>2</sup> *Id.* at 25.

<sup>3</sup> Centers for Disease Control, *Understanding the Epidemic* (updated Aug. 30, 2017), available at <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last visited Feb. 9, 2018).

<sup>4</sup> Drug Enforcement Administration, *supra* note 1, at 25.

<sup>5</sup> Centers for Disease Control, *Opioid Basics*, (updated Aug. 30, 2017), available at <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last visited Feb. 9, 2018).

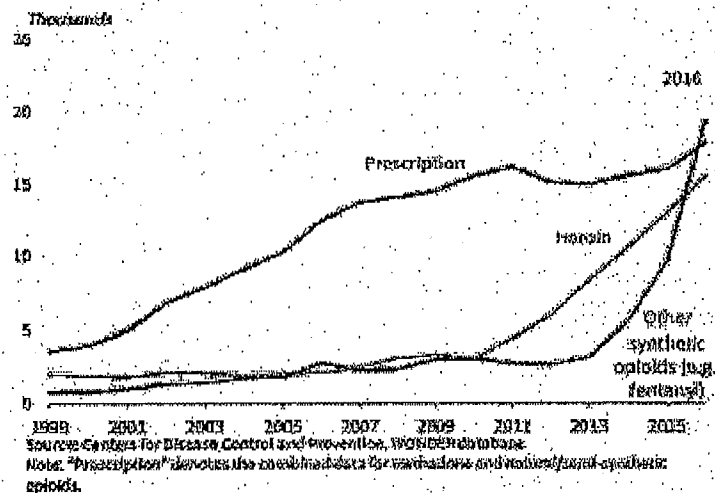
<sup>6</sup> Centers for Disease Control, *Understanding the Epidemic*, *supra* note 3.

<sup>7</sup> Centers for Disease Control, *Drug Overdose Death Data* (updated Dec. 19, 2017), available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited Feb. 9, 2018).



2. The national opioid crisis has “reached epidemic levels.”<sup>8</sup> The recent Economic Report of the President warns of chilling realities. The 350,000 American deaths from opioid overdose since 1999 amounts to 87% of the 405,399 American lives lost during World War II.<sup>9</sup> Staggeringly, drug overdose is now the *leading cause of death* for Americans under 50 years old and has removed 2.5 months from the average American’s life expectancy.<sup>10</sup> Since 1999, overdose deaths caused by prescription opioids have skyrocketed, also inducing a massive rise in heroin and other opioid overdose deaths—even as deaths caused by prescription opioids continues to rise.<sup>11</sup>

Figure 8-2. Overdose Deaths by Type of Opioid Involved, 1999–2016



3. Arkansas has been at the forefront of this trend. Overdose deaths in Arkansas have ballooned 262% from 5.1 per 100,000 citizens in the year 2000 to 13.4 per 100,000 in 2016.<sup>12</sup> One

<sup>8</sup> Chuck Rosenberg, Acting Administrator, Drug Enforcement Administration, 2015 *National Drug Threat Assessment Summary*, at iii, available at <https://www.dea.gov/docs/2015%20NTA%20Report.pdf> (last visited Feb. 23, 2018).

<sup>9</sup> *Economic Report of the President*, February 2018, at 292.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.* at 294.

<sup>12</sup> Nate Smith, M.D., M.P.H., Arkansas Department of Health, *Opioid Prescribing in Arkansas* (July 10, 2017), available at <http://www.arkleg.state.ar.us/assembly/2017/Meeting%20Attachments/430/15851/Opioid%20Handout-Nate%20Smith.pdf> (last visited Feb. 9, 2018).



thousand, sixty-seven people died from drug overdose deaths in Arkansas from 2013-2015, and at least half of those deaths were opioid-related.<sup>13</sup> In 2016 alone, Arkansas saw the number of drug overdose deaths rise to 401—at least 335 of which are opioid-related.<sup>14</sup>

4. Increased availability of these drugs corresponds with increased use and overdose.<sup>15</sup> As researchers have noted, “[t]he correlation between opioid sales, [opioid pain reliever]-related overdose deaths, and treatment seeking for opioid addiction is striking.”<sup>16</sup> It is no surprise, then, that Arkansas’s near-tripling in overdose deaths between 2000 and 2015 coincides with a span in which opioid sales have quadrupled.<sup>17</sup> The overwhelming growth in the supply of these drugs has ravaged the State of Arkansas, destroyed the lives of many of her citizens, and strained the capacity of State and local government to cope with the public-health crisis caused by the drugs’ rapid influx.

5. Arkansas has been particularly susceptible to the rapid expansion of opioid availability. There are now more opioid prescriptions in Arkansas than people. In fact, it has the second highest opioid prescription rate in the country, with doctors writing 114.6 opioid prescriptions for every 100 persons.<sup>18</sup> In less than five years, Arkansas’ opioid prescriptions rates

<sup>13</sup> Wesley Brown, *Arkansas prescription drug crisis worsens, President Trump addresses national opioid epidemic*, TALK BUSINESS & POLITICS (Aug. 8, 2017), available at <https://talkbusiness.net/2017/08/arkansas-prescription-drug-crisis-worsens-president-trump-addresses-national-opioid-epidemic/> (last visited Feb. 12, 2018).

<sup>14</sup> Arkansas Prescription Monitoring Program, *Drug Overdose Deaths in Arkansas 2000-2016*, available at [http://www.healthyarkansas.gov/images/uploads/pdf/Mortality\\_Report\\_-\\_2017\\_v3.pdf](http://www.healthyarkansas.gov/images/uploads/pdf/Mortality_Report_-_2017_v3.pdf) (last visited March 2, 2018); Wesley Brown, *Gov. Hutchinson, Arkansas health officials announce naloxone standards to curb opioid-related overdose*, TALK BUSINESS & POLITICS (Sept. 6, 2017), available at <https://talkbusiness.net/2017/09/gov-hutchinson-arkansas-health-officials-announce-naloxone-standards-to-curb-opioid-related-overdose/> (last visited Feb. 9, 2018).

<sup>15</sup> National Institute on Drug Abuse (NIDA), *Prescription Opioids and Heroin* (updated Jan. 2017), available at <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-abuse-heroin-use/increased-drug-availability-associated-increased-use-overdose> (last visited Feb. 9, 2018).

<sup>16</sup> Andrew Kolodny, David T. Courtwright, Catherine S. Hwang, Peter Kreiner, John L. Eadie, Thomas W. Clark, & Caleb Alexander, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANNUAL REV. OF PUB. HEALTH 559, 560-561 (2015).

<sup>17</sup> Arkansas Prescription Monitoring Program, *Drug Overdose Deaths in Arkansas 2000-2015*, available at [http://www.arkansaspmpp.com/files/2017/Mortality\\_Report\\_Final\\_v3.pdf](http://www.arkansaspmpp.com/files/2017/Mortality_Report_Final_v3.pdf) (last visited Feb. 12, 2018).

<sup>18</sup> Centers for Disease Control and Prevention, *U.S. State Prescribing Rates* (updated July 31, 2017), available at <https://www.cdc.gov/drugoverdose/maps/rxstate2016.html> (last visited Feb. 9, 2018).

have surged from eighth-most in the nation to second.<sup>19</sup> Drug companies sold 235,934,613 opioid pills across the state in 2016, making opioids both the top-selling class of prescription drug in Arkansas and more than twice as prevalent as the next highest-selling prescription drug class.<sup>20</sup> Drug companies sell enough opioids in Arkansas for every man, woman, and child to each take 80 pills per year.<sup>21</sup>

6. The National Bureau of Economic Research has concluded that economic conditions do not explain the current opioid epidemic and “that efforts to improve economic conditions in distressed locations, while desirable for other reasons, are not likely to yield significant reductions in drug mortality.”<sup>22</sup> In fact, the current epidemic is “related to the availability and cost of the drugs.”<sup>23</sup> In other words, the epidemic was directly caused, and is perpetuated, by the companies that manufacture and distribute opioids.

7. Drug manufacturers and wholesale distributors have ensured that opioid supplies abound in Arkansas and have made it one of the well-stocked states in the country. According to Retail Summary Reports from the DEA’s Automation of Reports and Consolidated Orders System (“ARCOS”) database, manufacturers and distributors supplied nearly two billion milligrams of opioids to Arkansas pharmacies in 2015, despite the State’s relatively small population.<sup>24</sup> The same year, Arkansas ranked number one in meperidine distribution per 100,000 people, number three in

<sup>19</sup> Compare Centers for Disease Control, *supra* note 14 with Centers for Disease Control and Prevention, *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines, United States, 2012*, 63 *Morbidity and Mortality Weekly Report* 563 (July 4, 2014), available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm> (last visited Feb. 13, 2018).

<sup>20</sup> Arkansas Department of Health, *Prescription Monitoring Program Annual Report January-December 2016*, available at [http://www.arkansaspmpp.com/files/2017/2016 Annual Report FINAL.pdf](http://www.arkansaspmpp.com/files/2017/2016%20Annual%20Report%20FINAL.pdf) (last visited Feb. 9, 2018).

<sup>21</sup> Wesley Brown, *Arkansas at front line of U.S. opioid epidemic*, TALK BUSINESS & POLITICS (Sept. 13, 2017), available at <https://talkbusiness.net/2017/09/arkansas-at-front-line-of-u-s-opioid-epidemic> (last visited Feb. 9, 2018).

<sup>22</sup> Christopher J. Ruhm, The National Bureau of Economic Research, *Deaths of Despair or Drug Problems?* (Jan. 2018), available at <http://www.nber.org/papers/w24188> (last visited Feb. 9, 2018).

<sup>23</sup> *Id.*

<sup>24</sup> Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *ARCOS 3 – Report 5, Statistics, Summary for Retail Drug Purchases by Grams WT, Reporting Period: 01/01/2015 to 12/31/2015*, available at [https://www.deadiversion.usdoj.gov/arcos/retail\\_drug\\_summary/2015/2015\\_rpt5.pdf](https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2015/2015_rpt5.pdf) (last visited Feb. 9, 2018).

codeine and tapentadol distribution, and number four in hydrocodone distribution.<sup>25</sup> Overall, Arkansas pharmacies received more milligrams of opioids per citizen than those of all but three other states.<sup>26</sup>

8. Abuse and addiction are the natural by-products of the over-supply of opioids saturating Arkansas. Opioids are highly addictive, and repeated exposure has been noted to cause structural changes in the brain that lead to addiction.<sup>27</sup> Research conducted at the University of Arkansas for Medical Sciences has shown just how dangerous even minimal exposure to opioids can be, finding that “[t]he probability of long-term opioid use increases most sharply in the first days of therapy,” and “the chances of chronic use begin to increase after the third day [of opioid] supplied and rise rapidly thereafter.”<sup>28</sup>

9. The overwhelming availability of these drugs has taken its toll on Arkansas in a variety of ways. In addition to the direct problems of adult addiction, abuse, and overdose, the opioid epidemic has created a ripple effect, touching lives across all age groups and straining public resources. Increased opioid use has been linked with increased emergency room visits for opioid-related problems and an increase in neonatal abstinence syndrome (“NAS”).<sup>29</sup> NAS is a constellation of symptoms resulting from drug use during pregnancy.<sup>30</sup> Opioid use by pregnant women increases the risk of NAS,<sup>31</sup> which increases the risk of pregnancy complications, including

<sup>25</sup> Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *ARCOS 3 – Report 4, Cumulative Distribution by State in Grams per 100,000 Population, Reporting Period: 01/01/2015 to 12/31/2015*, available at [https://www.deadiversion.usdoj.gov/arcos/retail\\_drug\\_summary/2015/2015\\_rpt4.pdf](https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2015/2015_rpt4.pdf) (last visited Feb. 9, 2018).

<sup>26</sup> Department of Justice, *supra* note 20.

<sup>27</sup> Kolodny, et al., *supra* note 12, at 560-561.

<sup>28</sup> Anuj Bhargava, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use*, 66 CDC Morbidity and Mortality Weekly Report 265 (March 17, 2017), available at <https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm> (last visited Feb. 9, 2018).

<sup>29</sup> Kolodny, et al., *supra* note 12, at 560-561.

<sup>30</sup> Arkansas Department of Health, *Neonatal Abstinence Syndrome in Arkansas 2000-2014*, available at [http://www.arkansasdoh.com/files/2017/NAS\\_Report\\_Final.pdf](http://www.arkansasdoh.com/files/2017/NAS_Report_Final.pdf) (last visited Feb. 9, 2018).

<sup>31</sup> Arkansas Department of Health, *supra* note 16.

maternal death and stillbirth.<sup>32</sup> The rate of NAS diagnosis in Arkansas increased more than ten-fold between 2000 and 2014.<sup>33</sup> Babies diagnosed with NAS spend five times more days in the hospital, and medical care costs increase ten-fold as compared to babies born without NAS.<sup>34</sup>

10. Older children have also been affected. According to Arkansas Attorney General Leslie Rutledge, presently “Arkansas ranks first in the nation for ages 12 to 17 in misuse of painkillers.”<sup>35</sup> In 2012, former Attorney General Dustin McDaniel noted that prescription drug abuse was plaguing Arkansas’s children, stating that “by the time Arkansas high school students have reached their senior year, roughly one in five has abused prescription drugs.”<sup>36</sup> For each age group, Arkansas ranks in the top 20 states for opioid abuse.<sup>37</sup>

11. In addition, the opioid epidemic is driving a dramatic increase in the number of children entering foster care.<sup>38</sup> The number of children in Arkansas’s foster care system has spiked more than 73%, growing from 3,806 in 2015 to 5,209 as of September 28, 2016.<sup>39</sup> Drug-endangered children are at increased risk of injury, death, physical and sexual assault, neglect, and perpetuation of the cycles of drug and child abuse.<sup>40</sup> In the 4th quarter of the State’s 2017 fiscal year, over half of children placed into the foster care system were placed because of substance

<sup>32</sup> Ayumi Maeda, Brian T. Bateman, Caitlin Clancy, Andreea Creanga, Lisa Leffert, *Opioid Abuse and Dependence during Pregnancy: Temporal Trends and Obstetrical Outcomes*, 121 ANESTHESIOLOGY 1158 (Dec. 2014).

<sup>33</sup> Arkansas Department of Health, *supra* note 26.

<sup>34</sup> *Id.*

<sup>35</sup> Wesley Brown, *supra* note 17.

<sup>36</sup> Dustin McDaniel, Attorney General, *Arkansas Prescription Drug Summit*, Conference Agenda (Apr. 26, 2012).

<sup>37</sup> Arkansas Department of Human Services, *State Targeted Response to Opioid Crisis*.

<sup>38</sup> Teresa Wiltz, *Drug Addiction Epidemic Creates Crisis in Foster Care*, STATELINE (Oct. 7, 2016), available at <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/10/07/drug-addiction-epidemic-creates-crisis-in-foster-care> (last visited Feb. 13, 2018).

<sup>39</sup> State Targeted Response (STR) to Opioid Crisis citing Brawner S. Director: *Foster spike's cause hard to pinpoint; some caseworkers erring on side of removal*, TALK BUSINESS & POLITICS (Nov. 29, 2016), available at <https://talkbusiness.net/2016/11/director-foster-spikes-cause-hard-to-pinpoint-some-caseworkers-erring-on-side-of-removal/> (last visited Feb. 13, 2018).

<sup>40</sup> Department of Justice, Office of Public Affairs, *Keeping Them Safe: The Task Force on Drug Endangered Children* (Aug. 17, 2010).

abuse by parents—and the vast majority of which involve drug abuse.<sup>41</sup> The same was true each quarter before that—55% of entries into the foster care system in the 3rd quarter were due to parental substance abuse,<sup>42</sup> 57% in the 2nd quarter,<sup>43</sup> and 53% in the 1st quarter.<sup>44</sup>

12. The fallout from the prescription opioid epidemic has also spawned a public health and criminal justice crisis stemming from increased use of the illegal drug heroin. Heroin use has been increasing every year.<sup>45</sup> Arkansas has seen the number of heroin-related hospitalizations increase more than eight-fold, from 42 in 2011 to 364 in 2015.<sup>46</sup> Opioid users graduate from prescription pills to heroin because it is cheaper, available, and it affects the same brain receptors to provide feelings of euphoria similar to prescription opioids.<sup>47</sup> Three in four heroin users also report use of prescription opioids,<sup>48</sup> and 80% of current heroin users report that their opioid use began with prescription opioids.<sup>49</sup> The CDC reports that overdose deaths involving heroin have more than tripled in the last four years, and the opioid epidemic is largely to blame.<sup>50</sup>

<sup>41</sup> Hornby Zeller Associates, Inc., *Quarterly Performance Report, 4th Quarter SFY 2017*, at 11 (produced for Arkansas Department of Health, Division of Children and Family Services), available at [http://humanservices.arkansas.gov/images/uploads/dcf/4th\\_Qtr\\_QPR\\_SFY\\_2017\\_FINAL.pdf](http://humanservices.arkansas.gov/images/uploads/dcf/4th_Qtr_QPR_SFY_2017_FINAL.pdf) (last visited Feb. 9, 2018).

<sup>42</sup> Hornby Zeller Associates, Inc., *Quarterly Performance Report, 3rd Quarter SFY 2017*, at 11 (produced for Arkansas Department of Human Services, Division of Children and Family Services), [http://humanservices.arkansas.gov/images/uploads/dcf/3rd\\_Qtr\\_QPR\\_SFY\\_2017\\_FINAL.pdf](http://humanservices.arkansas.gov/images/uploads/dcf/3rd_Qtr_QPR_SFY_2017_FINAL.pdf) (last visited Feb. 9, 2018).

<sup>43</sup> Hornby Zeller Associates, Inc., *Quarterly Performance Report, 2nd Quarter SFY 2017*, at 11 (produced for Arkansas Department of Human Services, Division of Children and Family Services), [http://humanservices.arkansas.gov/images/uploads/dcf/2nd\\_Qtr\\_SFY\\_2017\\_FINAL.pdf](http://humanservices.arkansas.gov/images/uploads/dcf/2nd_Qtr_SFY_2017_FINAL.pdf) (last visited Feb. 9, 2018).

<sup>44</sup> Hornby Zeller Associates, Inc., *Quarterly Performance Report, 1st Quarter SFY 2017*, at 11 (produced for Arkansas Department of Human Services, Division of Children and Family Services), <http://humanservices.arkansas.gov/images/uploads/dcf/1st%20Qtr%20SFY%202017%20FINAL.pdf> (last visited Feb. 9, 2018).

<sup>45</sup> Arkansas Department of Human Services, *supra* note 33.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> Kolodny, et al., *supra* note 12, at 560-561.

<sup>50</sup> Theodore Cicero, Matthew Ellis, Hilary Surratt, *The Changing Face of Heroin Use in the United States*, 71 J. AM. MED. ASSOC. 821 (July 2014).



13. Arkansas authorities have been active in attempting to ameliorate the epidemic. Over the past decade, the Arkansas Medical Board has disciplined over 80 physicians throughout the State for overprescribing, diverting, and abusing opioids. Medical Board files include the complaints of numerous Arkansas parents that have lost their children to prescription opioid overdose.

14. Recently, the Drug Enforcement Administration (“DEA”)’s Little Rock office and various Arkansas law enforcement agencies took part in the “Operation Pilluted” campaign targeting abuse of prescription opioids in Arkansas, which former U.S. Attorney Christopher Thyer branded as “perhaps the greatest drug problem Arkansas currently faces.”<sup>51</sup> As a result of Operation Pilluted, the DEA and Arkansas law enforcement exposed eminent examples of opioid diversion throughout the State, including:

- a. Dr. Mahmood Ahmad, who from his Sherwood clinic colluded with Insys and internet pharmacy Linden Care to illegally prescribe Subsys fentanyl spray—one of the deadliest opioids and 100 times more powerful than morphine—in exchange for kickbacks, committing at least 121 violations of the Controlled Substances Act in the process;
- b. KJ Medical Clinic of Little Rock, from which federal prosecutors indicted 16 individuals in connection with the clinic’s long term hydrocodone diversion, including illegitimate prescriptions for approximately 287,500 10mg hydrocodone pills in a 10-month period, most of which were filled at local Bowman Curve Pharmacy.<sup>52</sup> Between just December 15, 2014 and March 6, 2015, Bowman Curve Pharmacy filled 1,484 prescriptions—only six of which were *not* from KJ Medical Clinic<sup>53</sup>;
- c. Dr. Richard Johns of Little Rock and at least 38 others’ oxycodone diversion enterprise in Lonoke, Pulaski, and White Counties, in which the doctor and his

<sup>51</sup> Department of Justice, U.S. Attorney’s Office, Eastern District of Arkansas, *140 Charged in Arkansas As Part of National Prescription Drug Initiative* (May 20, 2015), available at <https://www.justice.gov/usao-edar/pr/140-charged-arkansas-part-national-prescription-drug-initiative> (last visited Feb. 4, 2018).

<sup>52</sup> Linda Satter, *Former Little Rock doctor gets probation in pill mill case*, NORTHWEST ARKANSAS DEMOCRAT-GAZETTE (Apr. 1, 2017); Linda Satter, *Conway doctor pleads guilty in drug case*, NORTHWEST ARKANSAS DEMOCRAT-GAZETTE (Apr. 21, 2016).

<sup>53</sup> Linda Satter, *Conway doctor pleads guilty in drug case*, NORTHWEST ARKANSAS DEMOCRAT-GAZETTE (Apr. 21, 2016).

accomplices distributed at least 39,000 oxycodone and OxyContin pills with a street value of \$30 a piece<sup>54</sup>.

d. Perry County Food and Drug Store, from which a pharmacist diverted "tens of thousands of Schedule II, III, IV pills," likely including more than 49,000 oxycodone and 72,000 hydrocodone pills<sup>55</sup>; and

e. a hydromorphone diversion network in Little Rock that illegally distributed roughly 2,500 Dilaudid pills a month between the fall of 2013 and August 2014.<sup>56</sup>

15. Despite law enforcement efforts, prescription opioids continue to flood into the State of Arkansas and Plaintiff Counties and Cities, and the epidemic of addiction continues to plague their citizens.

16. All of the foregoing factors have dramatically increased demand for state, county, city, and medical services needed to respond to the additional problems created by the opioid epidemic. The epidemic has strained public funding and required public services that so far exceed the normal, expected costs that they are distinct from and unrelated to their normal provision and have resulted in a need for services above what the State, Counties, and Cities are able to currently provide. The relief requested in this case is necessary for the State, Counties, and Cities to adequately respond to the opioid epidemic.

17. Defendants' conduct has foreseeably exacted a financial burden on Arkansas citizens, including Plaintiffs. Plaintiffs have unnecessarily and jointly spent, and will continue to spend, considerable funds on costs directly attributable to the flood of opioids that Defendants unleashed upon the State, the Counties, the Cities and their citizens.

<sup>54</sup> Linda Satter, *Internist admits selling opioid prescriptions*, NORTHWEST ARKANSAS DEMOCRAT-GAZETTE (Mar. 3, 2017).

<sup>55</sup> Department of Justice, U.S. Attorney's Office, Eastern District of Arkansas, *Perryville Pharmacist Sent to Prison for 10 Years, to Pay \$850,000 for Role in Pill Scheme* (Sept. 27, 2017), available at <https://www.justice.gov/usao-edark/perryville-pharmacist-sent-prison-10-years-pay-850000-role-pill-scheme> (last visited Feb. 4, 2018); Linda Satter, *Ed pharmacist draws 10 years for pill scheme*, NORTHWEST ARKANSAS DEMOCRAT-GAZETTE (Sept. 28, 2017).

<sup>56</sup> Department of Justice, *supra* note 47.

18. To redress and punish these violations of law, Plaintiffs seek damages for the amounts they have paid in the past and will pay in the future, among other damages, compensation, and penalties.

**B. The Opioid Epidemic emerges from a conspiracy of greed.**

19. Defendants manufacture, market, distribute, dispense, and prescribe opioids, including brand-name drugs like Oxycontin and Percocet, and generics like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of common chronic pain (e.g., back pain, migraines, and arthritis), opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

20. However, by the late 1990s, and continuing today, opioid manufacturers began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. The White House itself blames Manufacturer Defendants for inciting the opioid epidemic: "[I]n response to claims that pain was under-treated and assurances from manufacturers that new opioid formulations were safe, the number of opioid prescriptions skyrocketed. What followed was an increase in the misuse of and deaths related to these prescriptions."<sup>57</sup>

21. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks, Manufacturer Defendants falsely and misleadingly, and contrary to the language of their drugs'

<sup>57</sup> *Economic Report of the President*, *supra* note 9, at 293.



labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Manufacturer Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support their claims.

22. Manufacturer Defendants disseminated these common messages to reverse the prevalent popular and medical understanding that opioids were not suitable for such use. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited for their support of the marketing messages. Borrowing a page from Big Tobacco's playbook, Manufacturer Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Manufacturer Defendants persuaded doctors and patients that what they had long known—that opioids are addictive drugs, unsafe in most circumstances

for long-term use—was untrue, and that the compassionate treatment of pain, in fact, *required* opioids.

23. Each Manufacturer Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use in Arkansas and continues to fail to correct its past misrepresentations.

24. Manufacturer Defendants also formed an opioid marketing enterprise in violation of Arkansas law for the purpose of illegally promoting the widespread use of opioids for chronic pain.

25. Manufacturer Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated \$11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain." This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin. Arkansas is now awash in opioids and engulfed in a public health crisis the likes of which has not been seen before.

26. While Manufacturer Defendants ignited the fires of the opioid epidemic, the Distributor Defendants fanned the flames. Controlling 85 to 90% of prescription opioid wholesale distribution, Distributor Defendants could and should have curbed the excess opioid supply in Arkansas, but they did not. Despite being required by Arkansas law to prevent unlawful opioid diversion, Distributor Defendants purposefully shunned their responsibilities to line their pockets at Arkansas' expense. The result of Arkansas's opioid crisis has been catastrophic. Opioids have become the main source of unintentional drug overdose in the state and, due to the vast supply of opioids, the number of annual deaths attributable to unintentional drug overdoses has rapidly increased in recent years. The dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors. Efforts by physicians to reverse course for a chronic pain patient with long term dependence on opioids are often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply these patients.

27. Prescription opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on Arkansas' local governments that address heroin use addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high.

28. Many Arkansas citizens suffer from chronic pain, which takes an enormous toll on their health, lives and families. These patients deserve both appropriate care and the ability to make informed decisions based on accurate and complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived Arkansas patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their

doctors, and health-care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

29. Defendants' conduct has also foreseeably exacted a financial burden on Arkansas citizens, including Plaintiffs. Plaintiffs have unnecessarily and jointly spent, and will continue to spend, considerable funds on costs directly attributable to the flood of opioids that Defendants unleashed upon the State and its citizens.

30. To redress and punish these violations of law, Plaintiffs seek damages for the amounts they have paid in the past and will pay in the future, among other damages, compensation, and penalties.

## II. PARTIES.

### A. Plaintiffs

31. Plaintiff, the STATE OF ARKANSAS, *ex rel.* Scott Ellington, the duly elected Second Judicial Circuit Prosecuting Attorney, the venue in which this action is brought, (hereinafter "the State") brings this suit "in favor of the State and in which the State is interested," "in the name of the State," and in the State's sovereign capacity pursuant to ARK. CODE ANN. § 16-106-101.

32. Plaintiff, ARKANSAS COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

33. Plaintiff, ASHLEY COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

34. Plaintiff, BAXTER COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

35. Plaintiff, BENTON COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

36. Plaintiff, BOONE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

37. Plaintiff, BRADLEY COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

38. Plaintiff, CALHOUN COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

39. Plaintiff, CARROLL COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

40. Plaintiff, CHICOT COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

41. Plaintiff, CLARK COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

42. Plaintiff, CLAY COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

43. Plaintiff, CLEBURNE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

44. Plaintiff, COLUMBIA COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

45. Plaintiff, CONWAY COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

46. Plaintiff, CRAIGHEAD COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

47. Plaintiff, CRAWFORD COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
48. Plaintiff, CROSS COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
49. Plaintiff, DALLAS COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
50. Plaintiff, DESHA COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
51. Plaintiff, FAULKNER COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
52. Plaintiff, FRANKLIN COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
53. Plaintiff, FULTON COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
54. Plaintiff, GARLAND COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
55. Plaintiff, GRANT COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
56. Plaintiff, GREENE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.
57. Plaintiff, HEMPSTEAD COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.



58. Plaintiff, HOT SPRING COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

59. Plaintiff, HOWARD COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

60. Plaintiff, INDEPENDENCE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

61. Plaintiff, IZARD COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

62. Plaintiff, JACKSON COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

63. Plaintiff, JOHNSON COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

64. Plaintiff, LAFAYETTE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

65. Plaintiff, LAWRENCE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

66. Plaintiff, LEE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

67. Plaintiff, LINCOLN COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

68. Plaintiff, LITTLE RIVER COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

69. Plaintiff, LOGAN COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

70. Plaintiff, LONOKE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

71. Plaintiff, MADISON COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

72. Plaintiff, MARION COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

73. Plaintiff, MILLER COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

74. Plaintiff, MISSISSIPPI COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

75. Plaintiff, MONROE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

76. Plaintiff, MONTGOMERY COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

77. Plaintiff, NEVADA COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant ARK. CODE ANN. § 14-14-102.

78. Plaintiff, NEWTON COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

79. Plaintiff, OUACHITA COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.



80. Plaintiff, PERRY COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

81. Plaintiff, PHILLIPS COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

82. Plaintiff, PIKE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

83. Plaintiff, POINSETT COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

84. Plaintiff, POLK COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

85. Plaintiff, POPE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

86. Plaintiff, PRAIRIE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

87. Plaintiff, RANDOLPH COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

88. Plaintiff, ST. FRANCIS COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

89. Plaintiff, SALINE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

90. Plaintiff, SCOTT COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

91. Plaintiff, SEARCY COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

92. Plaintiff, SEBASTIAN COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

93. Plaintiff, SEVIER COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

94. Plaintiff, SHARP COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

95. Plaintiff, STONE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

96. Plaintiff, UNION COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

97. Plaintiff, VAN BUREN COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

98. Plaintiff, WASHINGTON COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

99. Plaintiff, WHITE COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

100. Plaintiff, WOODRUFF COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

101. Plaintiff, YELL COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

102. Plaintiff, CLEVELAND COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

103. Plaintiff, CRITTENDEN COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

104. Plaintiff, PULASKI COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

105. Plaintiff, JEFFERSON COUNTY, ARKANSAS is a political subdivision of the State of Arkansas pursuant to ARK. CODE ANN. § 14-14-102.

106. Plaintiff, CITY OF LITTLE ROCK, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Pulaski County.

107. Plaintiff, CITY OF FORT SMITH, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Sebastian County.

108. Plaintiff, CITY OF SPRINGDALE, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Washington and Benton County.

109. Plaintiff, CITY OF JONESBORO, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Craighead County.

110. Plaintiff, CITY OF NORTH LITTLE ROCK, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Pulaski County.

111. Plaintiff, CITY OF CONWAY, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Faulkner County.

112. Plaintiff, CITY OF ROGERS, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Benton County.

113. Plaintiff, CITY OF PINE BLUFF, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Jefferson County.

114. Plaintiff, CITY OF BENTONVILLE, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Benton County.

115. Plaintiff, CITY OF HOT SPRINGS, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Garland County.

116. Plaintiff, CITY OF BENTON, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Saline County.

117. Plaintiff, CITY OF TEXARKANA, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Miller County.

118. Plaintiff, CITY OF SHERWOOD, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Pulaski County.

119. Plaintiff, CITY OF JACKSONVILLE, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Pulaski County.

120. Plaintiff, CITY OF MONTICELLO, ARKANSAS, is a municipal corporation of the State of Arkansas pursuant to ARK. CONST. art. 12, § 3 and ARK. CODE ANN. § 14-37-102, and is located in Drew County.

121. Each County is a "political subdivision of the state for the more convenient administration of justice and the exercise of local legislative authority" and "a body politic and corporate operating within specified geographic limitations established by law." ARK. CODE ANN. § 14-14-102. Thus the Counties serve as "the state's auxiliaries and instrumentalities in the administration of its government." *Bedmont v. Adkisson*, 593 S.W.2d 11, 17 (Ark. 1980). "The word 'county' signifies a portion of a state resulting from a division of the state into such areas for the better government thereof and the easier administration of justice." *Id.*

122. The State maintains a "County Aid Fund," recorded on the books of the Treasurer of the State, the Auditor of the State, and the Chief Fiscal Officer, from which it funds, in part, county services. ARK. CODE ANN. § 19-5-602. Moreover, the State requires and empowers the counties to provide numerous services that are severely strained because of the opioid epidemic. For example:

- a. All counties have a sheriff who is required to be a conservator of the peace in his or her county. ARK. CODE ANN. § 14-15-501. The Counties all maintain sheriff departments, which employ deputies to aid sheriffs in their statutory duties. Should the Counties lack sufficient resources to meet sheriff law enforcement obligations,

those obligations fall to the State. Arkansas law enforcement has been greatly impacted at the state, county, and city level by the opioid epidemic. The Counties have expended and will continue to expend enormous additional resources to fulfill their law enforcement obligations necessitated by Defendants' conduct in causing the opioid epidemic.

- b. Pursuant to ARK. CODE ANN. § 14-14-802(a), the Counties are required to provide the following necessary services to their citizens: (1) the administration of justice through the several courts of record of the county, (2) law enforcement protection services and the custody of persons accused or convicted of crimes, and (3) court and public records management, including registration, recording, and custody of public records. These services will hereinafter be referred to as "mandatory services." Due solely to the opioid epidemic caused by Defendants' actions, the Counties have been forced to expend monies and will continue to expend monies for mandatory services they otherwise would not have had to expend and in an amount far greater than they can afford. The State's delegation of state duties to the Counties as enumerated in § 14-14-802(a) does not eliminate the State's continuing obligations to its citizens. Because the Counties' revenues have been insufficient to underwrite the expanded cost of mandatory services caused by Defendants, the State of Arkansas has made and will continue to make the remaining payments.
- c. Pursuant to ARK. CODE ANN. § 14-14-802(b), the Counties are empowered to provide the following necessary services to their citizens: (1) emergency services, including ambulance, civil defense, fire prevention and protection, and juvenile detention; and (2) human services, including air and water pollution control, child care/youth and senior citizen services, public health and hospital care, public nursing and extended care, and social and rehabilitative care. Due solely to the opioid epidemic caused by Defendants' actions, the Counties have been forced and will continue to be forced to expend monies for these much-needed services they otherwise would not have had to expend and in an amount far greater than they can afford. The State's delegation of state duties to the Counties as enumerated in § 14-14-802(b) does not eliminate the State's continuing obligations to its citizens. Because the Counties' revenues have been and will continue to be insufficient to underwrite the expanded cost of these services caused by Defendants, the State of Arkansas has made and will continue to make the remaining payments.
- d. In administering the courts, counties supply a significant amount of the funding. In 2015, the counties reported \$64.1 million in costs while only generating \$18.1 million in revenues through county fees and costs, so the counties paid \$46 million into the courts.<sup>58</sup>
- e. Counties employ Drug Court Juvenile Intake and Probation Officers, who assist the courts with cases involving delinquent juveniles, dependent-neglected juveniles, or families in need of services. The State of Arkansas shares in the cost of one-half

<sup>58</sup> Arkansas Legislative Audit, Special Report, *Information Regarding the Arkansas Supreme Court, Court of Appeals, and Circuit Courts*, available at <http://www.arklegaudit.gov/pdf.aspx?id=SPSA01313> (last visited Feb. 9, 2018).



of the juvenile probation and intake officers' salaries up to \$15,000 per position, as provided under ARK. CODE ANN. §§ 16-13-327 through 328.

- f. The District Courts of the State of Arkansas bear the extraordinary cost of judicial proceedings in relation to Arkansas' opioid epidemic. Pursuant to ARK. CODE ANN. § 16-17-115 and 16-17-1106, the Counties are required to reimburse the State for one-half of the State's obligation to pay the salaries of the district judge and the chief district court clerk. These statutorily prescribed district court services will hereinafter be referred to as "mandatory services." Due solely to the opioid epidemic caused by Defendants' actions, the Counties have been and will continue to be forced to expend monies for mandatory services the additional cost of which they otherwise would not have had to expend and in an amount far greater than they can afford. The State's delegation of state duties to the Counties as enumerated in § 16-17-115 does not eliminate the State's continuing obligations to its citizens. Because the Counties' revenues have been and will continue to be insufficient to underwrite the expanded cost of mandatory services caused by Defendants, the State of Arkansas has made and will continue to make the remaining payments through the County Aid Fund.
- g. Pursuant to ARK. CODE ANN. § 16-10-201, *et seq.*, the State has statutory authority over and audits the municipal and county accounts pertaining to Arkansas' District Courts, and the State has statutory authority over and mandates the activities of cities and counties in relation to their required duties regarding Arkansas' District Courts. The State's authority extends to and directs the activities of all police departments, city or town marshals, sheriffs' offices, court clerks, court administrators, the city treasurers, the county treasurers, and the governing bodies of the cities and counties.
- h. Arkansas' opioid epidemic has caused a dramatic increase in the number of involuntary commitments throughout the State. While the jurisdiction for these commitments lies in the circuit courts, the Counties and Cities bear the increased costs of transporting those committed through their respective sheriffs' and police departments. While the Arkansas Department of Human Services promulgates the rules setting costs for individuals committed or those responsible for them, many cannot reimburse the State for the costs. Further, the State assigns the Counties the cost of appointed counsel for persons sought to be committed.

123. The State also maintains a "Municipal Aid Fund," recorded on the books of the Treasurer of the State, the Auditor of the State, and the Chief Fiscal Officer, from which the State funds, in part, city services. ARK. CODE ANN. § 19-5-601. Those city services are and will continue to be severely strained because of the opioid epidemic. For example:

- a. Pursuant to ARK. CODE ANN. §§ 14-52-101, the Cities have established police departments. The law enforcement performed by the City Police Departments

would fall to the State and/or the Counties should the Cities not possess sufficient resources to meet their law enforcement obligations. Arkansas law enforcement has been and will continue to be greatly impacted at the state, county, and city level by the opioid epidemic. The Cities have expended and will continue to expend enormous additional resources to fulfill their law enforcement obligations that were necessitated by the Defendants' conduct in causing the opioid epidemic. Cities have likewise expended and will continue to expend enormous additional resources responding to first responder calls, through their fire departments, that were necessitated by the Defendants' conduct in causing the opioid epidemic.

- b. The district courts bear extraordinary costs of judicial proceedings in relation to Arkansas' epidemic. Pursuant to ARK. CODE ANN. §§ 16-17-115 and 16-17-1106, the Cities are required to: (1) pay the operational expenses of the district court in that town or city, and (2) reimburse the State for one-half of the State's obligation to pay the salaries of the district judge and the chief district court clerk. Pursuant to ARK. CODE ANN. § 16-17-119, in those counties having a population of 250,000 or more inhabitants, the State requires the city or town in which the district courts are located to bear their applicable salaries and operation expenses. These statutorily prescribed district court services will hereinafter be referred to as "mandatory services." Due solely to the opioid epidemic caused by Defendants' actions, the Cities have been and will continue to be forced to expend monies for mandatory services the additional cost of which they otherwise would not have had to expend and in an amount far greater than they can afford. The State's delegation of state duties to the Cities as enumerated in § 16-17-115 does not eliminate the State's continuing obligations to its citizens. Because the Cities' revenues have been and will continue to be insufficient to underwrite the expanded cost of mandatory services caused by Defendants, the State of Arkansas has made and will continue to make the remaining payments through the Municipal Aid Fund.
- c. Pursuant to ARK. CODE ANN. §§ 16-10-201 *et seq.*, the State has statutory authority over and audits the municipal and county accounts pertaining to Arkansas' District Courts, and the State has statutory authority over and mandates the activities of cities and counties in relation to their required duties regarding Arkansas' District Courts. The State's authority extends to and directs the activities of all police departments, city or town marshals, sheriff's offices, court clerks, court administrators, the city treasurers, the county treasurers, and the governing bodies of the cities and counties.
- d. Pursuant to ARK. CODE ANN. §§ 16-21-115, a prosecuting attorney may designate a city attorney within the prosecutor's district to prosecute in the name of the State in the district courts violations of state misdemeanor laws occurring within the municipal limits and upon agreement by the city attorney.
- e. Arkansas' opioid epidemic has caused a dramatic increase in the number of involuntary commitments throughout the State. While the jurisdiction for these commitments lies in the circuit courts, the increased cost of transportation of those committed is born by the Counties and Cities through their sheriff's departments



and police departments. While, the Division of Aging, Adult, and Behavior Health Services of the Arkansas Department of Human Services promulgates the rules specifying the amounts to be fixed as costs as against the individuals committed or those responsible for same, many cannot reimburse the State for such costs.

**B. Manufacturer Defendants**

124. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Arkansas. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

125. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Arkansas. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA

sells all former Cephalon branded products through its "specialty medicines" division. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Arkansas, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain, Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Arkansas and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon.")

126. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its

principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock. J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.") Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Arkansas, including the opioid Duragesic. Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

127. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and no members of ACTAVIS LLC are citizens of Arkansas. Each of these Defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Allergan Plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis Plc acquired Allergan Plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. Allergan Plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit.

(Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.") Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Arkansas. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

128. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the U.S. and Arkansas. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Arkansas, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

129. VINTAGE PHARMACEUTICALS, LLC ("Vintage") is a limited liability company organized under the laws of the State of Delaware, with its principal place of business in Huntsville, Alabama. Vintage is a wholly-owned subsidiary of Endo International Plc and manufactures, promotes, sells, and distributes generic opioid products in the United States and Arkansas.

130. INSYS THERAPEUTICS, INC. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures, promotes, sells, and distributes a sublingual fentanyl spray under the brand name Subsys in the U.S. and Arkansas.

131. MALLINCKRODT PLC is a public limited liability company organized and existing under the laws of the State of Ireland, with its principal place of business in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt PLC manufactures, promotes, sells, and distributes branded opioids Exalgo, Roxicodone, Xartemis XR, and Methadose; and morphine sulfate extended release, fentanyl extended release, fentanyl citrate, oxycodone, hydrocodone, and other generic opioid products in the U.S. and Arkansas. MALLINCKRODT PHARMACEUTICALS ("Mallinckrodt Pharma") (Mallinckrodt PLC and Mallinckrodt Pharma are collectively referred to as "Mallinckrodt") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Hazelwood, Missouri. Mallinckrodt Pharma manufactures, promotes, sells, and distributes branded opioids such as Exalgo, Roxicodone, Xartemis XR, and Methadose; and morphine sulfate extended release, fentanyl extended release, fentanyl citrate, oxycodone, hydrocodone, and other generic opioid products in the U.S. and Arkansas.

132. MYLAN PHARMACEUTICALS INC. ("Mylan") is a company organized and existing under the laws of the State of West Virginia, with its principal place of business in Morgantown, West Virginia. Mylan manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—generic opioid pharmaceutical products in the United States and Arkansas.

133. SUN PHARMACEUTICALS INDUSTRIES, INC. ("Sun") is a corporation organized under the laws of the State of Michigan, with its principal place of business in Cranbury,

New Jersey. Sun manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—generic opioid pharmaceutical products in the United States and Arkansas.

134. AUROBINDO PHARMA USA, INC. (“Aurobindo USA”) is a corporation organized under the laws of the State of Delaware, with its principal place of business in Dayton, New Jersey. Aurobindo USA is a wholly-owned subsidiary of Aurobindo Pharma Ltd. and manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

135. AUROLIFE PHARMA LLC (“Aurolife”) is a limited liability company organized under the laws of the State of Delaware, with its principal place of business in Dayton, New Jersey. Aurolife is a wholly-owned subsidiary of Aurobindo USA and manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

136. LUPIN PHARMACEUTICALS, INC. (“Lupin”) is a corporation organized under the laws of the State of Delaware, with its principal place of business in Baltimore, Maryland. Lupin is a wholly-owned subsidiary of Lupin Ltd. and manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

137. COLLEGIUM PHARMACEUTICAL, INC. (“Collegium”) is a corporation organized under the laws of the State of Delaware, with its principal place of business in Canton,

Massachusetts. Collegium manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

138. BIODELIVERY SCIENCES INTERNATIONAL, INC. (“BSI”) is a corporation organized under the laws of the State of Delaware, with its principal place of business in Raleigh, North Carolina. BSI manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas. BSI licenses its branded fentanyl buccal soluble film Onsolis to Collegium.

139. SHIONOGI, INC. (“Shionogi”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Florham Park, New Jersey. Shionogi manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

140. ABBVIE, INC. (“AbbVie”), is a corporation organized under the laws of Delaware, with its principal place of business in North Chicago, Illinois. AbbVie manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas. ABBOTT LABORATORIES, INC. (“Abbott”) is a corporation organized under the laws of the State of Delaware, with its principal place of business in Chicago, Illinois. Before splitting from AbbVie in 2013, Abbott manufactured, promoted, sold, and distributed branded and generic opioid pharmaceutical products in the United States and Arkansas.

141. PERNIX THERAPEUTICS HOLDINGS, INC. ("Pernix") is a corporation organized under the laws of the State of Maryland, with its principal place of business in Morristown, New Jersey. Pernix manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

142. DAIICHI SANKYO, INC. ("Daiichi Sankyo") is a corporation organized under the laws of the State of Delaware, with its principal place of business in Parsippany, New Jersey. Daiichi Sankyo manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

143. FOREST LABORATORIES, INC. ("Forest Laboratories") is a wholly-owned subsidiary of Allergan and is a corporation organized under the laws of Delaware, with its principal place of business in New York, New York. FOREST PHARMACEUTICALS, INC. ("Forest Pharmaceuticals") is a wholly-owned subsidiary of Forest Laboratories and is a corporation organized under the laws of the State of Delaware, with its principal place of business in St. Louis, Missouri. (Forest Laboratories and Forest Pharmaceuticals are collectively referred to as "Forest"). Forest manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

144. MAYNE PHARMA INC. ("Mayne") is a corporation organized under the laws of the State of North Carolina, with its principal place of business in Paramus, New Jersey. Mayne manufactures, promotes, sells, and distributes—or at times relevant to this Complaint,



manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

145. APOTEX INC. ("Apotex") is a corporation organized and existing under the laws of Canada, with its principal place of business in Ontario, Canada. Apotex manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

146. WEST-WARD PHARMACEUTICALS CORP. ("West-Ward") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Eatontown, New Jersey. West-Ward merged with Roxane Laboratories, Inc. after the latter's acquisition by Hikma Pharmaceuticals Plc, and West-Ward manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas. Before its acquisition, Roxane Laboratories manufactured, promoted, sold, and distributed branded and generic opioid products in the United States and Arkansas.

147. GEMINI LABORATORIES, LLC ("Gemini") is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business in Bridgewater, New Jersey. Gemini manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

148. POLY-PHARMACEUTICALS, INC. ("Poly") is a corporation organized under the laws of the State of Alabama, with its principal place of business in Owens Cross Roads, Alabama. Forest Pharmaceuticals is in the business of manufacturing and selling branded and generic opioid

pharmaceutical products for the United States and Arkansas markets. Poly manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

149. AKORN, INC. (“Akorn”) is a corporation organized under the laws of the State of Louisiana, with its principal place of business in Lake Forest, Illinois. Akorn manufactures, promotes, sells, and distributes—or at all times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

150. VALEANT PHARMACEUTICALS NORTH AMERICA, LLC (“Valeant”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Bridgewater, New Jersey. Valeant manufactures, promotes, sells, and distributes—or at all times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

151. ECR PHARMACEUTICALS, INC. (“ECR”) is a wholly-owned subsidiary of Valeant and a corporation organized under the laws of the State of Delaware, with its principal place of business in Richmond, Virginia. ECR manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas markets.

152. DEPOMED, INC. (“Depomed”) is a corporation organized and existing under the laws of the State of California, with its principal place of business in Newark, California. Depomed manufactures, promotes, sells, and distributes—or at times relevant to this Complaint,

manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

153. VALIDUS PHARMACEUTICALS, LLC (“Validus”) is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business in Parsippany, New Jersey. Validus manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

154. EGALET CORPORATION (“Egalet”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Wayne, Pennsylvania. Egalet manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

155. VERNALIS THERAPEUTICS, INC. (“Vernalis”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Berwyn, Pennsylvania. Vernalis manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

156. UCB PHARMA, INC. (“UCB”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Smyrna, Georgia. UCB manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

157. XANODYNE PHARMACEUTICALS, INC. ("Xanodyne") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Newport, Kentucky. Xanodyne manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

158. VERTICAL PHARMACEUTICALS, INC. ("Vertical") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Bridgewater, New Jersey. Vertical manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

159. SENTYNL THERAPEUTICS, INC. ("Sentyln") is a corporation organized and existing under the laws of the State of Virginia, with its principal place of business in Solana Beach, California. Sentyln manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

160. RHODES TECHNOLOGIES, INC. is a corporation organized under the laws of the State of Delaware, with its principal place of business at Coventry, Rhode Island. RHODES TECHNOLOGIES L.P. is a general partnership organized under the laws of the State of Delaware, with its principal place of business in Coventry, Rhode Island (Rhodes Technologies, Inc. and Rhodes Technologies L.P. are collectively referred to as "Rhodes"). Rhodes are wholly-owned subsidiaries of Purdue Pharma, L.P. and manufacture, promote, sell, and distribute—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

161. SANDOZ, INC. is a corporation organized under the laws of the State of Colorado, with its principal place of business at Princeton, New Jersey. Sandoz manufactures, promotes, sells, and distributes—or at times relevant to this Complaint, manufactured, promoted, sold, and distributed—branded and generic opioid pharmaceutical products in the United States and Arkansas.

**C. Distributor Defendants**

162. AMERISOURCEBERGEN DRUG CORPORATION, is a Delaware corporation with a principal place of business in Chesterbrook, Pennsylvania, and distributes opioids within Arkansas.

163. CARDINAL HEALTH, INC. is an Ohio corporation with its principal office located in Dublin, Ohio, and distributes opioids within Arkansas.

164. McKESSON CORPORATION, is a Delaware corporation that has its principal place of business located in San Francisco, California, and distributes opioids within Arkansas.

165. Plaintiffs have named three (3) wholesale distributors which dominate 85% of the Market share for the distribution of prescription opioids. The “Big 3” are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. Each has been investigated and/or fined by the DEA for the failure to maintain effective controls against opioid diversion. Plaintiffs allege that each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into our community and that discovery will reveal others who likewise engaged in unlawful conduct.

**D. Retail Defendants**

166. LINDEN CARE, LLC (“Linden Care”) is a foreign limited liability company licensed in Arkansas as an out-of-state pharmacy. Linden Care’s principal place of business and corporate headquarters is located in Woodbury, New York. At all relevant times, Linden Care

served as a concierge pharmacy service specializing in filling, dispensing, and shipping pain medications throughout the United States, including Arkansas, using commercial shipping services. During the relevant time period, Linden was reportedly the leading pharmacy dispenser of fentanyl spray. Linden does not have physical retail pharmacies in Arkansas. Instead, it dispensed and shipped fentanyl spray to patients throughout the United States, and in Arkansas, by Federal Express. Between April 2014 and November 2015, Linden solicited and received from Arkansas prescriptions for fentanyl spray.

167. KJ MEDICAL MANAGEMENT, LLC ("KJ Medical Management") is a domestic limited liability company with its principal place of business in Little Rock, Arkansas. KJ Medical management owns and operates—or at times relevant to this Complaint owned and operated—KJ Medical Clinic in Little Rock, Arkansas. During the relevant time period, KJ Medical Clinic participated in an opioid diversion scheme with Dr. Jerry Reifeiss, Dr. Shawn Michael Brooks, Bowman Curve Pharmacy, and Kristen Holland.

168. CJN PHARMACY SERVICES, LLC ("CJN") is a domestic limited liability company with its principal place of business in Little Rock, Arkansas. CJN owns and operates—or at times relevant to this Complaint owned and operated—Bowman Curve Pharmacy in Little Rock, Arkansas. During the relevant time period, Bowman Curve Pharmacy participated in an opioid diversion scheme with KJ Medical Clinic, Dr. Jerry Reifeiss, Dr. Shawn Michael Brooks, and Kristen Holland.

169. PERRY COUNTY FOOD & DRUG, INC. is a domestic corporation with its principal place of business in Perryville, Arkansas. Perry County Food & Drug, Inc. owns and operates—or at times relevant to this Complaint owned and operated—the Perry County Food &

Drug retail pharmacy in Perryville, Arkansas. During the relevant time period, Perry County Food & Drug participated in an opioid diversion scheme with pharmacist Christopher Watson.

170. KRISTEN HOLLAND is a pharmacist who was licensed in Arkansas and practiced pharmacology at Bowman Curve Pharmacy in Little Rock, Arkansas. In connection with the Operation Pilluted campaign, Holland was charged with conspiracy to distribute controlled substances. Holland pleaded guilty to misprision of a felony and was sentenced to three years' probation.

171. CHRISTOPHER WATSON is a pharmacist who was licensed in Arkansas and practiced pharmacy at Perry County Food & Drug in Perryville, Arkansas. In connection with the Operated Pilluted campaign, Watson was charged with, *inter alia*, conspiracy to distribute controlled substances without an effective prescription, healthcare fraud, and structuring. Watson pleaded guilty to these counts and was sentenced to 120 months imprisonment.

**E. Physician Defendants**

172. MAHMOOD AHMAD, M.D. is a physician who was licensed in Arkansas and Alaska and practicing in the field of pain management at his medical practice in Sherwood, Arkansas. In October 2016, the Arkansas State Medical Board revoked Ahmad's medical license for gross negligence and professional incompetence arising from his practice of overprescribing high dose opioids. A few weeks earlier, Ahmad lost his license to practice in Alaska after that state's medical board ruled that his practices in prescribing opioids and treating patients posed "a clear and immediate danger to the public health and safety."

173. UNITED PAIN CARE, LTD ("UPC") is an Arkansas corporation that at all relevant times was providing health care services for profit in the State of Arkansas in Sherwood, Arkansas. UPC, through its employees and physicians, including Ahmad, was in the business of providing medical services through its agents, principles, and employees. At all material times,

Ahmad was the president, owner, and medical director of UPC. While an entity, UPC is included in "Physician Defendants" for sake of efficiency.

174. SHAWN MICHAEL BROOKS, M.D. is a physician who was licensed in Arkansas and Utah and practiced in the field of pain management at his medical practice, KJ Medical Clinic in Little Rock, Arkansas. In connection with the Operation Pilluted campaign, Dr. Brooks was charged with conspiracy to distribute controlled substances; the Arkansas State Medical Board entered an emergency suspension order suspending Dr. Brooks' license for overprescribing controlled substances and endangering Arkansas public health, safety, and welfare; and Dr. Brooks stipulated to his license's revocation from the Utah Division of Occupational and Professional Licensing. Dr. Brooks pleaded guilty to misprision of a felony and was sentenced to five years' probation.

175. RICHARD DUANE JOHNS is a physician who was licensed in Arkansas and practiced in the field of internal medicine. In connection with Operation Pilluted, Dr. Johns was charged with conspiracy to distribute controlled substances without an effective prescription, and the Arkansas State Medical Board entered an emergency suspension order suspending Dr. Johns' license for endangering Arkansas public health, safety, and welfare.

### III. JURISDICTION

176. This Court has jurisdiction over this matter pursuant to ARK. CODE ANN. § 16-13-201. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332 because the State of Arkansas is not a citizen for purposes of diversity jurisdiction. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked because the allegations are wholly state law claims. Nowhere do the parties plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law, nor do they bring this action or seek any relief on behalf of any person, a class,



or any group of persons that can be construed as a class. The relief sought by the Counties is in their respective capacities as political subdivisions of the State, and they seek no relief on behalf of any other person(s). The relief sought by the Cities is in their respective capacities as municipal corporations of the State, and they seek no relief on behalf of any other person(s). The parties specifically disclaim any such claims that would support removal of this action to a United States District Court on the basis of diversity or jurisdictional mandates under the Class Action Fairness Act of 2005 (28 U.S.C. §§ 1332(d), 1453, 1711-1715). The issues presented in the allegations of the instant, well-pleaded Complaint do not implicate significant or substantial federal issues and do not turn on the necessary interpretation of any federal law. The parties expressly aver that the only causes of action claimed, and the only remedies sought herein, are founded upon the statutory, common, and decisional laws of the State of Arkansas. The assertion of federal diversity jurisdiction over these claims would improperly disturb the constitutionally mandated and congressionally approved balance of federal and state responsibilities because federal jurisdiction does not exist over this case under 28 U.S.C. § 1332. "There is no question that a State is not a 'citizen' for purposes of the diversity jurisdiction." *Moor v. Alameda County*, 411 U.S. 693, 717, 93 S. Ct. 1785, 36 L. Ed. 2d 596 (1973). And, it is well settled that "a State's presence as a party will destroy complete diversity." *Mississippi ex rel. Hood v. AU Optronics Corp.*, 134 S. Ct. 736, 745 (2014) (citing *Missouri, K. & T. R. Co. v. Missouri Railroad and Warehouse Comm'rs*, 183 U.S. 53, 58-59, 22 S. Ct. 18 (1901)). Moreover, because this suit involves less than 100 plaintiffs and "[a]ccording to CAFA's plain text, a 'mass action' must involve monetary claims brought by 100 or more persons who propose to try those claims jointly as named plaintiffs," no federal jurisdiction exists. *Mississippi ex rel. Hood v. AU Optronics Corp.*, 134 S. Ct. 736, 739 (2014). Accordingly, any attempt by Defendants to remove this case to federal court would be without a

reasonable legal basis in fact or law. *See State of New Hampshire v. Perdue Pharma, et al.*, 17-cv-427-PB, USDC D. N.H., Remanding opioid complaint to state court on similar grounds (“A state’s action on behalf of its citizens does not become a class action merely because it seeks injunctive relief that benefits individual class members.”).

177. This Court has personal jurisdiction over Defendants as they conduct business in Arkansas, purposefully direct or directed their actions toward Arkansas, and/or have the requisite minimum contacts with Arkansas necessary to constitutionally permit the Court to exercise jurisdiction.

#### IV. VENUE

178. Venue is proper in this Court pursuant to ARK. CODE ANN. § 16-60-101(a) and (c) because Crittenden County is the county in which a substantial part of the events or omissions giving rise to these claims occurred; and Plaintiffs assert rights to relief against Defendants jointly, severally, and arising out the same transaction or occurrence, and common questions of law or fact will predominate over individual questions of law or material fact to each Plaintiff, this action can be maintained more efficiently and economically for all parties than if prosecuted separately, and the interests of justice support joinder of Plaintiffs in one action.

#### V. FACTUAL ALLEGATIONS

179. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients’ abilities to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

180. To take advantage of the lucrative market for chronic pain patients, each Manufacturer Defendant developed a well-funded marketing scheme based on deception. Each Manufacturer Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that benefited not only themselves and the third-parties who gained legitimacy when Manufacturer Defendants repeated those statements, but also other opioid manufacturers. These statements were contrary to the scientific evidence and targeted susceptible prescribers and vulnerable patient populations.

**A. Manufacturer Defendants used multiple avenues to disseminate their false and deceptive statements about opioids.**

181. Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Arkansas. Manufacturer Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State.

182. Manufacturer Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids.

183. Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2004. This amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

184. A number of Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website [opana.com](http://opana.com) a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arkansas.

185. Second, each Defendant promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices—and small-group speaker programs. Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent \$168 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10 million by Endo, and \$2 million by Actavis.

186. Manufacturer Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Manufacturer Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his

or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

187. Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Manufacturer Defendants know their detailing to doctors is effective.

188. Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in Arkansas as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

189. Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated

advertising. Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

190. Manufacturer Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.

191. Manufacturer Defendants also deceptively marketed opioids in Arkansas through unbranded advertising – i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Manufacturer Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

192. Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

193. Manufacturer Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials.

### 1. Key Opinion Leaders ("KOLs")

194. Manufacturer Defendants also spoke through a small circle of doctors who, were selected, funded, and elevated by Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

195. Manufacturer Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Manufacturer Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Manufacturer Defendants.

196. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Manufacturer Defendants created opportunities for KOLs to participate in research studies Manufacturer Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

197. Manufacturer Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Manufacturer Defendants were able to direct and exert control over each of these activities through their KOLs.

198. Pro-opioid doctors are one of the most important avenues that Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-



term opioid use. Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website In the Face of Pain failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

199. Thus, even though some of Manufacturer Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the State of Arkansas in Manufacturer Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

200. Manufacturer Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

201. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

202. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain



Foundation ("APF"), an advocacy organization almost entirely funded by Manufacturer Defendants.

203. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on Good Morning America in 2010 to discuss the use of opioids for long-term treatment of chronic pain. On this widely-watched program, broadcast in Arkansas and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

204. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist." Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."

205. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of

numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Manufacturer Defendants (including nearly \$2 million from Cephalon).

206. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

207. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

208. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, Managing Patient's Opioid Use: Balancing the Need and the Risk. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach Arkansas doctors.

209. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and his co-author wrote in a book entitled Avoiding Opioid Abuse While

Managing Pain (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.” Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”

210. These KOLs are non-party co-conspirators in this case.

## 2. Front Groups

211. Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Manufacturer Defendants, these “Front Groups” generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Manufacturer Defendants.

212. These Front Groups depended on Manufacturer Defendants for funding and, in some cases, for survival. Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Manufacturer Defendants made sure that the Groups would generate only the messages Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.

213. Manufacturer Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American

Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Educators ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

214. The most prominent of Manufacturer Defendants' Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at \$1.7 million.

215. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Arkansas' citizens.

216. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue) Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored Responsible Opioid Prescribing, a publication sponsored by Cephalon and Purdue), all of whom served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

217. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its

budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from Manufacturer Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

218. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide “patient representatives” for Manufacturer Defendants’ promotional activities, including for Purdue’s Partners Against Pain and Janssen’s Let’s Talk Pain. APF functioned largely as an advocate for the interests of Manufacturer Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

219. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

220. APF assisted in other marketing projects for drug companies. One project funded by another drug company—APF Reporter’s Guide: Covering Pain and Its Management (2009)—recycled text that was originally created as part of the company’s training document.

221. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state

Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?"

222. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Manufacturer Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Manufacturer Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

223. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

224. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Manufacturer Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

225. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the

annual event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Manufacturer Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

226. AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”

227. AAPM’s staff understood they and their industry funders were engaged in a common task. Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

228. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Manufacturer Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors’ prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications.



Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

229. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

230. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

231. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been



cited 732 times in academic literature, were disseminated in Arkansas during the relevant time period, are still available online, and were reprinted in the Journal of Pain.

232. Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

233. In this way and others, Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy.

234. These Front Groups are non-party co-conspirators in this case.

B. **The U.S. Senate Homeland Security and Governmental Affairs Committee February 2018 Minority Staff Report recognizes collusive opioid promotion between Manufacturer Defendants and Front Groups.**

235. On February 12, 2018, U.S. Senator Claire McCaskill of the Senate Homeland Security and Governmental Affairs Committee (“HSGAC”) released the second congressional report resulting from her investigation into opioid manufacturers and distributors.<sup>59</sup> Focusing on financial ties between the manufacturers and third party advocacy groups—i.e., the Front Groups—the report disclosed that Defendants Purdue, Janssen, Mylan, Depomed, and Insys made nearly \$9 million in payments to advocacy groups in the field of chronic pain and opioid use between February 2012 and March 2017.<sup>60</sup> The same five manufacturers made over \$1.6 million in payments to physicians affiliated with the advocacy groups since 2013, while all opioid manufacturers paid the same physicians over \$10 million in the same time period.<sup>61</sup>

<sup>59</sup> HSGAC Minority Staff Report, *Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, Fueling an Epidemic, Report Two (Feb. 12, 2018), available at <https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups> (last visited Feb. 19, 2018).  
<sup>60</sup> *Id.* at 1-3.

<sup>61</sup> *Id.* at 3.

236. The HGSAC report recognizes a direct correlation between payments and sales. For instance, Insys's payments to Front Groups rose sharply in 2012—when it began selling Subsys fentanyl spray.<sup>62</sup> The company's revenues and profits skyrocketed between 2013 and 2015, and its stock increased 296% between 2013 and 2016.<sup>63</sup> Similarly, Janssen's payments to Front Groups ceased as soon as it sold its major opioid brand Nucynta to Depomed in 2015; Depomed's Front Group payments promptly tripled.<sup>64</sup>

237. Senator McCaskill's report mirrors widespread recognition of Manufacturer Defendants' glaring collusion with Front Groups to promote opioid use and oppose all efforts to combat abuse:

Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain—the first national standards for prescription opioid and a key response to the ongoing epidemic.

The fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioid-friendly messaging.<sup>65</sup>

The report concluded:

As a 2011 study in the *American Journal of Public Health* noted, a tension exists between the status of advocacy organizations as “among the most influential and trusted stakeholders in U.S. health policy,” and the reality that their “positions

<sup>62</sup> Id. at 5.

<sup>63</sup> Id. (citing Joseph Walker, *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, WALL STREET JOURNAL (Nov. 22, 2016), available at <https://www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968> (last visited Feb. 19, 2018); Matthew Herper, *An Opioid Spray Showered Billionaire John Kapoor In Riches. Now He's Feeling the Pain*, FORBES (Oct. 25, 2016), available at <https://www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/#2cf376a76e3f> (last visited Feb. 19, 2018)).

<sup>64</sup> Id.

<sup>65</sup> Id. at 1.

closely correspond to the marketing aims of pharmaceutical and device companies.”<sup>66</sup> The findings in this report indicate that this tension exists in the area of opioids policy—that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use.<sup>67</sup>

**C. Manufacturer Defendants’ marketing scheme misrepresented the risks and benefits of opioids.**

238. To convince doctors and patients in Arkansas that opioids can and should be used to treat chronic pain, Manufacturer Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Manufacturer Defendants made claims that were not supported by or were contrary to the scientific evidence. Regardless, Manufacturer Defendants have not corrected these claims, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

**1. Manufacturer Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use.**

239. To convince doctors and patients that opioids are safe, Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher

<sup>66</sup> *Id.* at 17 (quoting Sheila M. Rothman et al., *Health Advocacy Organizations and the Pharmaceutical Industry: An Analysis of Disclosure Practices*, 101(4) AM. J. PUB. HEALTH 602 (Apr. 2011)).

<sup>67</sup> *Id.*

opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

240. First, Manufacturer Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that

most people do not develop an addiction problem.” A similar statement appeared on the Endo website [www.opana.com](http://www.opana.com).

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”

f. Janssen currently runs a website, [Prescriberesponsibly.com](http://Prescriberesponsibly.com) (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”

g. Purdue sponsored APF’s A Policymaker’s Guide to Understanding Pain & Its Management – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[].” This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon in Arkansas minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

241. These claims are contrary to longstanding scientific evidence.

242. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.” Endo had claimed on its [www.opana.com](http://www.opana.com) website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State found that Endo

had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements in Arkansas.

243. Second, Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Manufacturer Defendants called this phenomenon “pseudoaddiction” – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

b. Janssen sponsored, funded, and edited the Let’s Talk Pain website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated

pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated.”

e. Purdue sponsored a CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting opioid.

244. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”

245. Even one of the Manufacturer Defendants has effectively repudiated the concept of pseudoaddiction. In finding that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the State of New York, in



its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in Arkansas.

246. Third, Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. Endo paid for a 2007 supplement in the Journal of Family Practice, written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."



c. As recently as 2015, Purdue has represented in scientific conferences that “bad apple” patients—and not opioids—are the source of the addiction crisis and that once those “bad apples” are identified, doctors can safely prescribe opioids without causing addiction.

247. The CDC confirms the falsity of these misrepresentations. Its 2016 Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—“for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

248. Fourth, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

249. For example, a CME sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days. And Purdue sponsored APF’s A Policymaker’s Guide to Understanding Pain & Its Management, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.

250. Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug cravings,

anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.” The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

251. Fifth, Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Manufacturer Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

a. Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Based on Actavis’s

acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled Understanding Your Pain: Taking Oral Opioid Analgesics, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dosage escalations are "sometimes necessary," even unlimited

ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled Overview of Management Options that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.

252. These claims conflict with the scientific evidence.

253. Finally, Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

254. More specifically, Manufacturer Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

255. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was “designed to be, or is crush resistant.” The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that “[n]o studies” support the

notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies—even when they work—“do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.”

256. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Manufacturer Defendants successfully convinced doctors and patients to discount those risks.

**2. Manufacturer Defendants grossly overstated the benefits of chronic opioid therapy.**

257. To convince doctors and patients that opioids should be used to treat chronic pain, Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. Again, this claim is not supported by scientific evidence. Despite this, Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Manufacturer Defendants failed to correct these false and deceptive claims, they continue to make them today.

258. For example, Manufacturer Defendants falsely claimed that long-term opioid use improved patients’ function and quality of life. Some illustrative examples are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients’ function.

e. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.

f. Cephalon and Purdue sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids “give [pain patients] a quality of life we deserve.” The guide was available online until APF shut its doors in 2012.

g. Endo’s NIPC website painknowledge.com claimed in 2009 that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, Let’s Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

j. Purdue sponsored the development and distribution of APF’s A Policymaker’s Guide to Understanding Pain & Its Management, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 and is still available online today.

k. Purdue’s, Cephalon’s, Endo’s, and Janssen’s sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

259. These claims find no support in the scientific literature.

260. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours—a fact that Purdue has known at all times relevant to this action. According to Purdue’s own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and a “substantial number” of

chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

261. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell Arkansas doctors that OxyContin lasts a full 12 hours.

262. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Arkansas by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Arkansas Pain Initiative in support of Purdue, those amici represented:

Oxycontin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleeps through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, Oxycontin has been a miracle medication.

**3. Manufacturer Defendants also engaged in other unlawful, unfair, and fraudulent misconduct.**

263. Purdue unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high



rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action—even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as “an organized drug ring.” In doing so, Purdue protected its own profits at the expense of public health and safety.

264. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, Purdue continues to profit from the prescriptions of such prolific prescribers.

265. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

**D. Manufacturer Defendants targeted susceptible prescribers and vulnerable patient populations.**

266. As a part of their deceptive marketing scheme, Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including

Arkansas. For example, Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Manufacturer Defendants' misrepresentations.

267. Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

**E. Although Manufacturer Defendants knew that their marketing of opioids was false and deceptive, they fraudulently concealed their misconduct.**

268. Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the

harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.

269. Moreover, at all times relevant to this Complaint, Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

270. Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, [painknowledge.org](http://painknowledge.org), which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

271. Finally, Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Manufacturer Defendants' deceptive messages was not apparent to medical

professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiffs.

272. Thus, Manufacturer Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that Plaintiffs now assert. Plaintiffs did not know of the existence or scope of Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

**F. By increasing opioid prescriptions and use, Manufacturer Defendants' deceptive marketing scheme has fueled the Opioid Epidemic and devastated Arkansas communities.**

273. Manufacturer Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

274. Manufacturer Defendants' deceptive marketing scheme caused and continues to cause doctors in Arkansas to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Manufacturer Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Manufacturer Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Manufacturer Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

275. Manufacturer Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

276. The escalating number of opioid prescriptions written by doctors who were deceived by Manufacturer Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Arkansas. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

277. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

278. Contrary to Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids, and therefore could have been prevented had Manufacturer Defendants' representations to prescribers been truthful. Numerous doctors and

substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

279. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. Opioids are by far the most commonly prescribed class of substances in Arkansas. When compared to previous drug overdose epidemics in Arkansas, the current prescription drug epidemic is responsible for considerably more deaths, and the epidemic will continue unabated absent relief from the Court.

280. Manufacturer Defendants' deceptive marketing scheme has also had a significant detrimental impact on children in Arkansas in a number of ways. The overprescribing of opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household. Furthermore, children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more difficult and expensive to handle. Although the foster care system in Arkansas is managed by the State, all Plaintiffs bear many of the additional costs caused by Defendants' actions.

281. The overprescribing of opioids for chronic pain caused by Manufacturer Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Arkansas who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts. Babies with NAS typically require extensive hospital stays as they withdraw.

282. Opioid addiction is now the primary reason that Arkansas' citizens seek substance abuse treatment. The number of emergency medical services ("EMS") runs for suspected opioid-related overdose has also increased. The costs associated with the increase in medical treatments are borne in part by Plaintiffs.

283. Manufacturer Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities throughout Arkansas. Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

284. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite efforts to curtail it, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including: doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. In fact, a 2005 study by The Center on Addiction and Substance Abuse at Columbia University revealed that, by that time, 20.9% of pharmacies nationwide had stopped stocking certain medications such as OxyContin and Percocet, in order to protect themselves from robbery. This ongoing diversion of prescription narcotics creates a lucrative marketplace.

285. The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as

well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration. This results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers and law enforcement.

286. Manufacturer Defendants knew and should have known about these harms that their deceptive marketing has caused. Manufacturer Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Manufacturer Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew—and, indeed, intended—that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

287. Manufacturer Defendants' causal role is not broken by the involvement of doctors. Manufacturer Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Manufacturer Defendants also were able to harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

**G. Distributor Defendants likewise breached their duties to Plaintiffs.**

288. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including the Defendants Cardinal, McKesson, and AmerisourceBergen, which together account



for 85 to 90 percent of all revenues from drug distribution in the United States, estimated to be at \$378.4 billion in 2015. The distributors then supply opioids to hospitals, pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

289. Each participant in the supply chain shares the responsibility for controlling the availability of prescriptions opioids. Opioid “diversion” occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use.

290. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

291. Like all people, Distributors Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct—and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another—is under a duty to exercise reasonable care to prevent the threatened harm.

292. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the Arkansas Controlled Substances Act, ARK. CODE ANN. §§ 5-64-101, *et seq.*; the Arkansas Uniform Narcotic Drug Act, *id.* §§ 20-64-201, *et seq.*; and Arkansas Department of Health regulations promulgated thereunder, ARK. ADMIN. CODE §§ 007.07.1-I, *et seq.* These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants’ violation of these requirements shows that they failed to meet the relevant standard of conduct that society expects from them.

293. The Arkansas CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity who manufactures, distributes, or dispenses opioids must obtain a registration with the Arkansas Department of Health and the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the licit to the illicit marketplace, and there is great potential for harm to the general public.

294. All opioid distributors are required to maintain effective controls against opioid diversion.

295. To prevent unauthorized users from obtaining opioids, Arkansas law creates a distribution monitoring system for controlled substances. At the heart of this system are registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system which monitors the flow of Schedule II controlled substances from their point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' controlled substances acquisition/distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

296. In addition to filing acquisition/distribution transaction reports, Arkansas law requires each registrant to maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.

See ARK. CODE ANN. § 20-64-209. It is a violation of Arkansas law for any person to negligently fail to abide by the recordkeeping and reporting requirements.

297. In order to maintain registration, Arkansas law requires distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. ARK. ADMIN. CODE § 007.07.2-II-III.

**H. Distributor Defendants knew or should have known they were facilitating widespread opioid diversion.**

298. The problem of opioid diversion in the supply chain has been widely publicized for years. Numerous publications, studies, federal agencies, and professional organizations have highlighted the epidemic rate of opioid abuse and overdose rates in communities in Arkansas, as well as throughout the United States.

299. The Distributor Defendants were on notice that their own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" that stressed the critical role of each member of the supply chain in distributing controlled substances.

300. These industry guidelines further provided: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

301. Opioid distributors have themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

302. For example, a Cardinal executive recently claimed that it uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

303. At the very least, these assurances about constantly eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to reasonably follow through.

304. Thus, in addition to the obligations imposed by Arkansas law, through their own words and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic.

305. Despite these kinds of statements, the Distributor Defendants have knowingly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties.

306. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States. Again in 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. Just several months ago, in December 2016, a Department of Justice press released announced that, in connection with the CSA violations, the United States "Reaches \$34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act." In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Instead, Cardinal's opioid shipments to the pharmacy increased—to almost two million doses of oxycodone in one year—while other comparable pharmacies were receiving approximately 69,000 doses/year.

307. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson agreed to pay a \$13.25 million civil fine. After the 2008 settlement, McKesson was supposed to change its ways and act tougher towards opioid diversion. But it did not do so. Again in 2015, McKesson found itself in the middle of allegations concerning its failure to provide effective controls against opioid diversion. In early 2017 it was reported that McKesson agreed to pay \$150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

308. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes.

309. Although distributors have been penalized by law enforcement authorities, they remain obstinate. Instead of changing their behavior, they pay millions of dollars in fines as a cost of doing business in an industry which generates billions of dollars in revenue. In an October 2017 interview on "60 Minutes," former head of the DEA Office of Diversion Control Joe Rannazissi, who spent over a decade combating the national opioid epidemic, put it bluntly:

This is an industry that's out of control. What they want to do is what they want to do and not worry about what the law is. If they don't follow the law in drug supply, people die. That's just it, people die.

This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices that distribute them out to people who had no need for those drugs.

Interviewer: Who are these distributors?

Rannazissi: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90% of the drugs going downstream.

Interviewer: You know the implication of what you're saying . . . that these big companies knew that people were pumping drugs into American communities that were killing people.

Rannazissi: That's not an implication; that's a fact. That's exactly what they did.<sup>68</sup>

**I. Distributor Defendants' misconduct has injured and continues to injure Plaintiffs.**

310. The Distributor Defendants had the ability and duty to prevent opioid diversion, which presented a known or foreseeable danger of serious injury to Arkansas and Plaintiffs. But they failed to do so.

311. The Distributor Defendants have supplied quantities of prescription opioids in and around Arkansas with the actual or constructive knowledge that the opioids were ultimately being consumed by Arkansas' citizens for non-medical purposes. Many of these shipments should have been stopped or investigated, but the Distributor Defendants negligently or intentionally failed to do so.

312. Each Distributor Defendant knew or should have known that the amount of opioids that it allowed to flow into Arkansas was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

<sup>68</sup> Bill Whitaker and Joe Rannazissi, *The Whistleblower*, CBS 60 MINUTES (Oct. 15, 2017).

313. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing and prescribing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around Arkansas; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies.

314. The Distributor Defendants made little to no effort to visit the pharmacies servicing Arkansas to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses.

315. The compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing Arkansas, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

316. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in and around Arkansas with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

317. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,

and death. It is also reasonably foreseeable that many of these injuries will be suffered by Arkansas citizens, and that the costs of these injuries will be shouldered by Plaintiffs.

318. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic of Arkansas, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, and illegal transactions.

319. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed in and around Arkansas were being dispensed based on invalid or suspicious prescriptions.

320. The Distributor Defendants were aware of widespread prescription opioid abuse in and around Arkansas, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas—and in such quantities, and with such frequency—that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

321. The use of opioids by Arkansas citizens who were addicted or who did not have a medically-necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If any of the Distributor Defendants adhered to effective controls to guard against diversion, Arkansas, its citizens, and Plaintiffs would have avoided significant injury.

322. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into Arkansas. Their participation and cooperation in a common enterprise has foreseeably caused injuries to the citizens of Arkansas and financial damages to Plaintiffs. The



Distributor Defendants knew full well that Arkansas and its citizens, including Plaintiffs, would be unjustly forced to bear the costs of these injuries and damages.

323. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to relatively small communities primarily serving Arkansas citizens showed an intentional or reckless disregard for the safety of Arkansas and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of Arkansas and its citizens.

324. There have been monumental costs associated with the treatment of patients addicted to prescription opioids as well.

325. Nationally, claims involving workers who take opioids are almost four times more likely to reach costs of over \$100,000 than claims involving workers without opioids because opioid patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that a patient will be on work disability one year later. A prescription for opioids as the first treatment for a workplace injury doubles the average length of the claim.

326. While the use of opioids has taken an enormous toll on the State of Arkansas, its residents, and Plaintiffs, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

**J. Insys, Linden Care, UPC, and Ahmad's Arkansas Scheme.**

**1. The Fraudulent Scheme to Illegally Promote Fentanyl Spray**

327. Insys directed and engaged in a conspiracy with certain health care providers, including Dr. Ahmad and UPC, to write Subsys fentanyl spray prescriptions for patients using

bribes and kickbacks. The conspirators also made material misrepresentations regarding the patients' conditions, their needs for the drug, and their prior or current uses of other drugs during the prior authorization process in order to get payment for the fentanyl spray. As a result, patients across the country, including Plaintiffs' citizens, received fentanyl spray and suffered its side effects even though they were unqualified to use it.

**a. Insys's Illegal Kickbacks**

328. One of the necessary components to Insys's plan to expand the market for fentanyl spray was to co-opt health care professionals to prescribe the drug to non-cancer patients for common pain. Insys accomplished this by paying illegal kickbacks to clinicians, including Ahmad, who had the legal permission to write prescriptions for potent narcotics. Insys provided some, but not all, of the kickbacks through a sham front organization called the "Insys Speaker Program."

329. Through the speaker program, Insys paid health care professionals speaking fees, also referred to as an "honoraria," so long as they prescribed Subsys in high volumes. Using pharmacy data from third parties, Insys tracked and targeted the top prescribers. Because Insys focused on obtaining one or two doctors to write at least 30 Subsys prescriptions per month, it targeted prescribers running pain clinics with high-volume practice.

330. To disguise the real purpose of the money exchange, Insys described the fees as compensation for giving an educational talk on Subsys to colleagues and other potential prescribers at a "meeting." But many, if not all, of the "meetings" consisted only of the speaker and the sales representative in attendance; in some cases, they never took place. This did not matter to Insys. As then Vice President of Sales Alec Burlakoff stated to one sales representative while telling her not

to worry about speaker doctors' communications skills: "They do not need to be good speakers, they need to write a lot of [Fentanyl Spray prescriptions]." <sup>69</sup>

331. Insys specifically designed its program to direct payments only to those physicians who were dedicated to prescribing Subsys in high volumes. For instance, in September 2012, then Vice President of Sales Alec Burlakoff emphasized to the sales force the critical connection between speaker program fees and volume prescriptions:

If your speaker does not have at least 20 patients on Subsys (QTD), he or she should not be booked to speak at this juncture. You should cancel or suspend your programs until you and your manager have had ample chance to think this investment entirely through.

332. Burlakoff re-emphasized the purpose of the speaker programs to his sales force, telling them that they "must hold off on the conduction of these valuable speaker programs," until they knew "for absolute sure" that "if you use a specific speaker that the program will yield positive results." At the company's national sales meeting days later, Burlakoff again emphasized that a "critical success factor" in selling Subsys was to schedule a "consistent number of [Insys Speaking Programs] with top 20 targets." By the spring of 2013, the company's speaker payment plan was in full force. Burlakoff emphasized the critical nature of the program to the success of the company when admonishing the sales force:

I said it a thousand times. [Insys Speaking Programs] are the most important thing you will do to increase your business. ISP's are basically the ONLY thing you should be focusing on to increase your sales.

333. Burlakoff explained to his sales force what he meant by praising his top five sales representatives:

The below 5 names mentioned at the top of the company rankings—literally have their entire business being driven by basically 1 customer . . . [These top five sales

<sup>69</sup> U.S. v. Burlakoff, No. 1:16-cr-10343-ADB, Doc. 1 (D. Mass. Dec. 6 2016) (alteration in original).

representatives] found a customer to own and they packed the proverbial suitcase and moved in . . . Every winning team, must have their "MVP player."

It is and has always been your assignment to find this key player. If you have not found this doctor, throw the decile list, call list, routing, ROO list, etc. out the window. You have to start prospecting and develop a key doctor.

334. In another e-mail to his sales force, Burlakoff encouraged them to develop one or two prescribers from whom they could generate prescriptions on demand:

The goal is 1 rx per day . . . Are you still calling on multiple doctors a day giving a 'stand up message' in the hallway. If so, you don't stand a chance of lasting in this market. Do you have 1 or 2 customers whom [sic] have now become your best friend, that you rely on at least 1 rx per day and are you visiting this office every single day. If the answer is no, you are truly in a very bad situation.

335. For at least the three years between 2012 and 2015, the Insys speaker program allowed Insys to pay kickbacks to clinicians who prescribed fentanyl spray in high volumes and dramatically increased profits of the company. The brazen kickback conspiracy between Insys and prescribers of large amounts of fentanyl spray, including Ahmad and UPC, eventually got the attention of federal authorities.

336. On December 6, 2016, a federal grand jury indicted six former Insys executives, including the founder and owner John Kapoor, former CEO Michael Babich and Burlakoff, on charges of conspiracy to violate the federal anti-kickback statute for their role in the speaker fee scheme. Without identifying him by name, the indictment described Dr. Ahmad as one of ten clinician co-conspirators.

**b. Ahmad's Kickbacks**

337. After serving as Resident Medical Officer at University Hospital in Malaysia, Dr. Ahmad trained at Yale University in both Anesthesia and Pain Management between 1993 and 1998. In 2004, Dr. Ahmad became Director of Anesthesia and Pain Medicine at St. Vincent

Medical Center in Sherwood, Arkansas. During that same time period, and up until his license was suspended, he also served as Medical Director of the United Pain Care Clinic in Sherwood.

338. While serving as Medical Director at UPC, Ahmad owned and managed the pain clinic in Sherwood, where he saw as many as 75-100 patients per day. Ahmad treated few, if any, cancer patients. In or about the fall of 2012, Insys identified Ahmad as a target doctor. In September 2012, the company's Arkansas sales representative advised Insys senior management that the pharmacy next to Ahmad's office (a Pharmacy which Ahmad owned), had been forced to close because it was selling too many opioids. Insys further suspected that Ahmad and the pharmacy might be under investigation for over-prescribing opioids. Internal communications stated:

9/7 — . . . I have been unable to reach . . . Dr. Ahmad or his office manager for at least a month. The pharmacy which is located in the same stand-alone building was shut down due to the high percentage of opioids being dispensed. It has recently been opened but is unable to stock opioids. I spoke to . . . [my sales manager] and we are both under the opinion that they may be under investigation. I will follow up in 3-4 weeks to let things settle down.

339. The Arkansas sales representative also told senior management that Ahmad was "[v]ery pleased with . . . [the fentanyl spray]", but that he has "had difficulty with insurance coverage lately." He noted that the Pharmacy located within same building "cannot order CII Rx from distributors due to the ratio of opioids to other Rx. See once every week."

340. Armed with knowledge that Ahmad's pharmacy had been closed for dispensing too many opioids, was forbidden from selling more, and that Dr. Ahmad may be under investigation, Insys ignored the facts and continued to recruit Ahmad to become a fentanyl spray prescriber.

341. On or about October 8, 2012, the Arkansas sales representative for Insys sent corporate headquarters another update, this one to advise corporate that over dinner, Ahmad

guaranteed that he would write more fentanyl spray prescriptions than the company could imagine, once he was able to fill them at his pharmacy and start receiving his speaker fees.

10/5-RSM Rich Simon and I took ... Dr Ahmad and his office manager to dinner and turned things around 180 degrees. We set out a plan to conduct dinner programs for ... Dr. Ahmad to speak at his request.

Dr. Ahmad was not able to receive schedule two drugs in his buildings pharmacy which prevented his writing our drug. Rich Simon and I have been speaking to [the] pharmacist, ... [the Director of Trade and Distribution for the Company] & ... Dr. Ahmad to resolve the issue but have a guarantee from ... Dr. Ahmad to have "more scripts than we can handle" once the pharmacy issue is resolved and he begins to speak.

342. The investigation of Ahmad and his pharmacy continued into 2013. In or about April 2013, the Insys sales manager for Arkansas notified headquarters that she had cancelled scheduled Speaker Programs for Ahmad because he was not giving Insys enough business. In or about July 2013, the Arkansas sales manager sent another email to the assigned sales representative and senior management noting:

"Dr. Ahmad never wrote in Q2 and so far he has not written in Q3. I truly don't believe he is worth any more of your time especially since he is in AR. I am perplexed by his prescribing habits."

343. By the fall of 2013, Ahmad was writing one fentanyl spray prescription per week. But everything soon changed when Insys hired a new sales representative who had a history with Ahmad and was soon assigned directly to him. When the sales manager complained about the assignment, the company's Vice-President of Sales responded, stating:

[t]he current rep did not eat what he killed. He did not KILL anything, he merely braised the doctor! ... I need and want the business TODAY. I need to see if ... [the new sales representative] can bring me what the other rep could not. I need ... [the new sales representative] to make his living off this doctor. This is my job.

344. The sales manager received the message loud and clear, and Ahmad was soon in the fold. During the first quarter of 2014, Ahmad was paid for eight (8) Speaker Program events,

which generated big returns. By the end of March 2014, Ahmad had gone from writing one fentanyl spray prescription per week to as many as 30. Ahmad also went from having Speaker Program events cancelled for lack of prescriptions to receiving more speaking fees at higher rates. Many of the events Ahmad attended were mere social gatherings also attended by friends and office staff, and involved no presentation regarding fentanyl spray.

345. During 2014 and 2015, as a direct part of executing the scheme, Insys paid Dr. Ahmad approximately \$150,000.00 in kickbacks under the speaker program. In exchange, Ahmad wrote more than 1,450 fentanyl spray prescriptions while actively engaged in the scheme to defraud. During that same time, Ahmad is believed to have been the largest fentanyl spray prescriber in Arkansas, and one of the largest in the country.

**c. Insys misled insurers for reimbursement.**

346. Paying kickbacks to prescribing health care providers to incentivize writing fentanyl spray prescriptions for non-cancer patients was an important step in the Insys scheme. But unless someone agreed to pay for the fentanyl spray, Insys and Defendants knew the plan would fail.

347. Fentanyl spray is expensive and the only practical way that most patients could pay for the medication was through insurance—either private insurance, Medicare, or Medicaid. But insurers typically require prior authorization before they approve payment to the pharmacy. If the insurer or its agent denies authorization, most patients will request a more affordable alternative covered by insurance, and Insys loses profits. As a consequence, the pre-authorization screening process posed a significant hurdle to the Insys scheme to promote and sell fentanyl spray.

348. During 2012, insurers were regularly denying pre-authorization requests for fentanyl spray. In November 2012, for example, an internal Insys analysis showed that insurers were approving only about 30% of fentanyl spray pre-authorization requests. To address the



problem, Insys devised a plan to deceive insurers into granting pre-authorizations and thereby increase sales of fentanyl spray.

349. In January 2013, Insys launched what it described as the Insys Reimbursement Center (IRC). The IRC was a call-center at Insys corporate headquarters used to fraudulently obtain pre-authorizations for fentanyl spray prescriptions from insurers. The leader of the IRC was Elizabeth Gurrieri, an Insys employee, who was given the title of Manager of Reimbursement Services. In that role, she supervised and instructed the IRC employees until July 2016.

350. The employees working in the IRC were designated to receive significant financial incentives in the form of group and individual bonuses to boost the rate of pre-authorizations. They also received pressure from management, including Gurrieri, who according to one former company employee, told IRC employees to improve their rate of approvals because "Dr. Kapoor's (the company chairman) not happy, we have to get these approvals up."

351. The IRC employees used a number of nefarious, deceptive, and illegal techniques to meet the demands. For example, Insys directed members of its reimbursement unit to falsely represent that patients for whom they were seeking pre-authorization had cancer despite knowledge to the contrary. In fact, Insys employees were trained to answer questions from the insurers or their agents using a deceptive script, sometimes called "the spiel". When insurers asked, as part of the pre-authorization process, whether the patient suffered from breakthrough cancer pain, the Insys employee was told to say "[t]he physician is aware that the medication is intended for the management of breakthrough cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)."

352. The script deliberately omitted the word "cancer" in order to mislead the insurers and their agents. IRC employees were also taught to falsify the medical histories of patients,



fraudulently asserting that a patient had a cancer diagnosis when that was untrue and that fentanyl spray was being prescribed for a different diagnosis.

353. In addition, Insys concealed that the pre-authorization calls were coming from the company and not the prescriber's office. Ordinarily, insurers wanted to talk directly to their insured or the prescriber's office to collect necessary information. Knowing that fact, Insys employees hid outgoing phone numbers on caller ID and, if required to leave a phone number for a return call, provided an Insys 1-800 number rather than the prescribing physician's phone number. IRC employees were told to represent to insurers that they were calling from the doctor's office or "on behalf" of a doctor or with a doctor's office.

354. The IRC scheme for deceiving insurance companies to approve payment for fentanyl spray was extraordinarily successful. Within a few months, the approval for pre-authorization went from about 30% in November 2012, to 75% (according to a Board of Directors presentation in July 2013), to 100% (according to a Board of Directors presentation in November 2013).

355. The Insys Board of Directors knew that the company lacked the policies and monitoring procedures to prevent the IRC employees from manipulating the pre-authorization process. They were advised by outside consultants to prepare specific policies and operating procedures to prevent fraudulent and misleading communications by the IRC employees. But, the Board never did so. In June 2017, Elizabeth Gurrieri, the Insys employee who managed the IRC, pled guilty in federal court to conspiracy to commit wire fraud for her role in directing the deceptive and fraudulent conduct described above.

**d. Linden Care aided and assisted in the scheme.**

356. The Insys scheme to profit by marketing and promoting fentanyl spray included one other player: a pharmacy willing to dispense such large amounts of the medication and look

the other way. Linden Care, a New York pharmacy specializing in supplying opioids and pain medicine, was just the pharmacy. It turned a blind eye to what Insys was doing and shipped fentanyl spray to patients throughout the United States. Linden Care filled approximately 50% of the sales of fentanyl spray in the United States and most of the prescriptions written by Ahmad.

357. Linden Care was formed in New York in 2006 to provide concierge pharmacy services. It specialized in filling, dispensing, and shipping pain medications throughout the country via mail/commercial shipping services, most of which related to treatment of chronic disease and pain management. In essence, Linden Care was engaged in the practice of mail-order pharmacology, by and through its agents and employees, who were obligated to use professional skill, knowledge and care from their education, training and standards.

358. At all times relevant to the Complaint, Linden Care ignored and subverted its legal duties in dispensing fentanyl spray and was willfully blind and reckless in the manner in which it operated.

359. Defendants Insys, Linden Care, UPC, and Ahmad conducted a nationwide illegal scheme to market and sell one of the most potent and addicting opioids in the world, fentanyl spray under the brand name Subsys, which also directly targeted Arkansas citizens. Through kickbacks and bribes of doctors and other health care professionals, and other fraudulent means, Insys, Linden Care, UPC, and Ahmad collectively made hundreds of millions of dollars while exposing Plaintiffs' citizens to the drug's extraordinary risks, including addiction, abuse, and, in many cases, death.

K. Additional Arkansas Diversion Schemes Exposed by Operation Pilluted

1. The KJ Medical Clinic, Dr. Shawn Michael Brooks, Dr. Jerry Reifeiss, Bowman Curve, and Kristen Holland Opioid Diversion Scheme.

360. In May of 2015, federal authorities arrested Dr. Shawn Michael Brooks, Kristen Holland, and five others at KJ Medical Clinic, formerly Artex Medical Clinic, and Bowman Curve Pharmacy—both in Little Rock.<sup>70</sup>

361. A “pill mill” where individuals obtained prescriptions for narcotic drugs without having legitimate need,” KJ Medical Clinic had been the target of a coordinated investigation by the DEA and Arkansas law enforcement since July of 2014.<sup>71</sup> After his arrest, Dr. Brooks admitted to writing “illegitimate prescriptions” for at least 156,630 10mg hydrocodone pills during his tenure at KJ Medical Clinic.<sup>72</sup> Likewise, Dr. Jerry Reifeiss, now deceased, admitted to writing illegitimate prescriptions for 110,044 10mg hydrocodone pills at KJ Medical Clinic during just over a 3-month period.<sup>73</sup> A pharmacist reported that every KJ Medical Clinic patient she encountered had a “trinity” prescription for a benzodiazepine, carisoprodol, and the branded opioid Norco—manufactured by Watson and/or Actavis.

362. Beginning in November of 2014, KJ Medical Clinic staff directed recipients to fill their illegitimate prescriptions at Bowman Curve Pharmacy.<sup>74</sup> Of the 1,484 prescriptions filled at Bowman Curve between December 15, 2014 and March 6, 2015, only six did not originate from KJ Medical Clinic.<sup>75</sup>

<sup>70</sup>Department of Justice, *supra* note 47.

<sup>71</sup>Department of Justice, U.S. Attorney's Office, Eastern District of Arkansas, *140 Charged In Arkansas As Part of National Prescription Drug Initiative*, available at <https://www.justice.gov/usao-edar/pr/140-charged-arkansas-part-national-prescription-drug-initiative> (last visited Feb. 9, 2018).

<sup>72</sup>Linda Satter, *Arkansas Democrat-Gazette*, *Pill mill's doctor gets probation* (Apr. 1, 2017).

<sup>73</sup>Linda Satter, *Northwest Arkansas Democrat-Gazette*, *Conway doctor pleads guilty in prescription drug case* (Apr. 21, 2016).

<sup>74</sup>Department of Justice, *supra* note 55.

<sup>75</sup>Linda Satter, *supra* note 57.

363. Dr. Reifeiss pleaded guilty to one count of conspiracy to distribute hydrocodone without an effective prescription,<sup>76</sup> and Dr. Brooks and Holland pleaded guilty to misprision of a felony.<sup>77</sup> Dr. Brooks and Holland were sentenced to five and three years' probation, respectively.<sup>78</sup>

## 2. The Perry County Food & Drug and Christopher Watson Opioid Diversion Scheme.

364. Federal DEA authorities took Christopher Watson into custody in January of 2015 following a roughly six-month investigation into the opioid diversion scheme at Perry County Food & Drug pharmacy in Perryville.<sup>79</sup>

365. In November of 2014, DEA agents fabricated a hydrocodone and alprazolam prescription, and an undercover agent went to fill it at Perry County Food & Drug.<sup>80</sup> Watson acknowledged that the prescription was forged, gave the agent specific instructions on how to make it look legitimate, and filled it.<sup>81</sup> Further DEA investigation revealed that Watson "sold tens of thousands of Schedule II, III, and IV pills and other pharmaceuticals from the pharmacy shelves after hours and forged prescriptions to account for the missing pills, and filled fraudulent prescriptions presented by pharmacy customers."<sup>82</sup> Indeed, a pharmacy audit revealed that more than 49,000 oxycodone and more than 72,000 hydrocodone pills were missing after Watson's arrest.<sup>83</sup>

<sup>76</sup> U.S. v. Reifeiss, No. 4:15-cr-00101-JM, Doc. 371 (E.D. Ark. Apr. 20, 2016).

<sup>77</sup> U.S. v. Brooks, No. 4:15-cr-00101-JM, Doc. 382 (E.D. Ark. May 10, 2016); U.S. v. Holland, No. 4:15-cr-00101-JM, Doc. 294 (E.D. Ark. Feb. 10, 2016).

<sup>78</sup> U.S. v. Brooks, No. 4:15-cr-00101-JM, Doc. 655 (E.D. Ark. Mar. 31, 2017); U.S. v. Holland, No. 4:15-cr-00101-JM, Doc. 474 (E.D. Ark. July 15, 2016).

<sup>79</sup> Department of Justice, U.S. Attorney's Office, Eastern District of Arkansas, *Perry County Pharmacist Arrested On Federal Drug Charge* (Jan. 28, 2015), available at <https://www.justice.gov/usao-edar/pr/perry-county-pharmacist-arrested-federal-drug-charge> (last visited Feb. 9, 2018).

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> Department of Justice, U.S. Attorney's Office, Eastern District of Arkansas, *Perryville Pharmacist Sent to Prison for 10 Years, to Pay \$850,000 for Role in Pill Scheme* (Sept. 27, 2017), available at <https://www.justice.gov/usao-edar/pr/perryville-pharmacist-sent-prison-10-years-pay-850000-role-pill-scheme> (last visited Feb. 9, 2018).

<sup>83</sup> *Id.*

366. McKesson was Perry County Food & Drug's wholesale supplier.<sup>84</sup> A pharmacist that had worked at Perry County Food & Drug for 26 years testified that McKesson was able to adequately supply opioids until Watson became involved at the pharmacy.<sup>85</sup> A pharmacy technician that worked at Perry County Food & Drug for roughly one year testified that, after Watson became involved, the pharmacy usually reached its controlled substances limit with McKesson on the ninth day of each month.<sup>86</sup> Unsurprisingly, she believed that "orders placed by [Perry County Food & Drug were] excessive in light of the number of prescriptions that [were] actually filled there."<sup>87</sup>

367. Watson pleaded guilty to conspiracy to distribute hydrocodone without an effective prescription, healthcare fraud, and structuring<sup>88</sup> and was sentenced to 120 months imprisonment.<sup>89</sup>

### 3. The Dr. Richard Duane Johns Opioid Diversion Scheme

368. In May of 2015, the Lonoke County Sheriff's Office took Dr. Johns into custody in connection with a long-standing oxycodone diversion enterprise, for which federal authorities indicted Dr. Johns and 18 others.<sup>90</sup>

369. The investigation into Dr. Johns originated under tragic circumstances: the overdose death of a 25-year-old man from oxycodone fraudulently prescribed by Dr. Johns.<sup>91</sup> The investigation revealed that Dr. Johns wrote at least 187 fraudulent oxycodone prescriptions, which

<sup>84</sup> Department of Justice, Drug Enforcement Administration, Perry County Food & Drug; Decision and Order, 80 Fed. Reg. 70083, at 70099.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> U.S. v. Watson, No. 4:15-cr-00038-JM, Doc. 581 (E.D. Ark. Oct. 5, 2016).

<sup>89</sup> U.S. v. Watson, No. 4:15-cr-00038-JM, Doc. 809 (E.D. Ark. Sept. 28, 2017).

<sup>90</sup> Department of Justice, Drug Enforcement Administration, Eastern District of Arkansas, *Local Physician And 18 Others Charged in Federal Prescription Drug Distribution Indictment* (Sept. 2, 2015), available at <https://www.justice.gov/usao-edar/pr/local-physician-and-18-others-charged-federal-prescription-drug-distribution-indictment> (Feb. 9, 2018).

<sup>91</sup> *Id.*; Owen Moritz, Arkansas Business, *One Bad Doctor: Richard Johns Pill Mill Scheme Leads to Death of One, Endanger Dozens* (Mar. 13, 2017).

his co-conspirators filled and distributed on the street in Lonoke County alone during just a twelve-month period.<sup>92</sup> This amounted to approximately 16,830 oxycodone pills with a street value of \$505,000.<sup>93</sup>

370. Dr. Johns' diversion enterprise extended also into Pulaski and White Counties, where Dr. Johns would write oxycodone prescriptions in individual's names—in many cases, having never examined or even met them—and selling them for \$500 apiece.<sup>94</sup> Prescriptions were filled at local pharmacies, and oxycodone pills were sold on the street for \$30 each.<sup>95</sup> All told, "Dr. Johns was responsible for illegally distributing at least 39,000 pills, with a street value of more than \$1,000,000."<sup>96</sup>

371. Dr. Johns pleaded guilty to conspiracy to distribute and dispense Schedule II controlled substances without an effective prescription<sup>97</sup> and was sentenced to 108 months imprisonment.<sup>98</sup>

**L. The Arkansas opioid diversion exposed by federal and state investigation is only the tip of the iceberg.**

372. The specific examples discussed above represent only a sample of opioid diversion taking place throughout the State of Arkansas and Plaintiff Counties and Cities. Operation Pilluted, which exposed several Arkansas schemes, was the product of an "aggressive campaign" coordinated as a "national effort" between the DEA and law enforcement of four states.<sup>99</sup> Likewise,

<sup>92</sup> Department of Justice, *supra* note 74.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> Department of Justice, Drug Enforcement Administration, Eastern District of Arkansas, *Physician Admits to Illegally Distributing 39,000 Pills, Pleads Guilty to Federal Conspiracy* (March 2, 2017), available at <https://www.justice.gov/usao-edar/pr/physician-admits-illegally-distributing-39000-pills-pleads-guilty-federal-conspiracy> (last visited Feb. 9, 2018).

<sup>97</sup> *U.S. v. Johns*, No. 4:15-cr-00224-BSM, Doc. 333 (E.D. Ark. Mar. 2, 2017).

<sup>98</sup> *U.S. v. Johns*, No. 4:15-cr-00224-BSM, Doc. 504 (E.D. Ark. Aug. 8, 2017).

<sup>99</sup> See Department of Justice, *supra* note 55.

Insys, Linden Care, UPC, and Ahmad were exposed by FBI investigation into their illegal fentanyl distribution and kickback scheme.<sup>100</sup> The sheer volume of opioid prescriptions per capita, supply per capita, overdoses, and criminal activity in Arkansas demonstrate that the exposed operations are only the tip of the iceberg. Discovery will reveal the massive scope of opioid diversion throughout this State.

## VI. CAUSES OF ACTION

### COUNT I

#### Negligence/Gross Negligence (Against All Defendants)

373. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

374. Defendants are all in the chain of manufacturing, distributing, and dispensing dangerous controlled substances.

375. Based upon the Defendants' (a) knowledge and foreseeability of the effects of their actions or inactions and (b) control over the chain of manufacturing and supply as detailed throughout this Complaint and identified further herein, Defendants owe a duty of reasonable care in the manufacture, distribution, dispensing, and prescribing of opioids.

376. Likewise, based upon the Defendants' (a) knowledge and foreseeability of the effects of their actions or inactions and (b) control over the chain of manufacturing and supply as detailed throughout this Complaint and identified further herein, Defendants owe a duty of care not to endanger public health, welfare, or safety.

<sup>100</sup> Department of Justice, U.S. Attorney's Office, District of Massachusetts, *Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct. 26, 2017), available at <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering> (last visited Feb. 9, 2018).

377. Knowledge, control, and reasonable care by these Defendants are evidenced by the Arkansas Controlled Substances Act ("CSA"), the Arkansas Uniform Narcotic Drug Act ("UNDA"), and their accompanying regulations promulgated by the Arkansas Department of Health.

378. Schedule II controlled substances have "high potential for abuse," which "may lead to severe psychic or physical dependence," despite having a currently accepted medical use. ARK. CODE ANN. § 5-64-205; ARK. ADMIN. CODE § 060.00.1-7.

379. Arkansas law restricts manufacturers' and distributors' ability to manufacture and distribute Schedule II controlled substances like opioids by, among other things, requiring them to register to manufacture or distribute opioids and maintain effective controls against diversion of the controlled substances that they manufacture or distribute.

380. Arkansas Department of Health regulations require practitioners—which include manufacturers, wholesalers, and retailers of controlled substances—to maintain effective controls against opioid diversion. ARK. ADMIN. CODE § 007.07.2-II-III.

381. Department of Health regulations also require physicians and retail pharmacies to ensure that opioid prescriptions are issued for legitimate medical purposes. ARK. ADMIN. CODE § 007.07.2-II-VIII. Prescriptions "issued to an addict or habitual user of controlled substances, not in the course of professional treatment but for the purpose of providing the user with controlled substances sufficient to keep him/her comfortable by maintaining his/her use, is not a prescription" under the regulations. *Id.* at § 007.07.2-II-VIII(2).

382. The Arkansas CSA, UNDA, and their accompanying regulations, exist to prevent public harm threatened by narcotic drugs, which by definition are "dangerous to the public health" and "promotive of addiction-forming or addiction-sustaining results upon the user that threaten"



harm to the public health, safety, or morals[.]” ARK. CODE ANN. § 5-64-101(16)(A)(i). In failing to maintain effective controls against their diversion and illegitimate use, it is foreseeable that controlled substances will be prescribed for illegitimate purposes, diverted by corrupt retailers, and abused by the public that have fallen victim to their “high potential for abuse.” ARK. CODE ANN. § 5-64-205. Likewise, it is foreseeable that states and counties, and cities, including Plaintiffs, will face extraordinary costs in responding to the ensuing epidemic in, *inter alia*, law enforcement, incarceration, court costs, medical treatment, blight, lost tax revenue, lost productivity, and other areas. Further, Defendants had actual knowledge of these types of activities and their effects.

383. In addition, the Arkansas UNDA imposes specific record-keeping requirements on manufacturers and wholesalers who are required to maintain detailed records of all inventory of narcotic drugs received by and disposed of by them. ARK. CODE ANN. § 20-64-209. The information required to be collected and maintained includes dates of production and distribution and contact information of the persons to whom or for whose use the drugs were sold, administered or dispensed. These requirements serve to prevent diversion and non-medical use of the Manufacturer and Distributor Defendants’ products, as well as other controlled substances.

384. The Manufacturer Defendants and Distributor Defendants further owed Plaintiffs duties to be forthright and honest with Arkansas enforcement authorities regarding their products and to disclose the true risk of addiction associated with the use of opioids. The Manufacturer Defendants and Distributor Defendants had control over their own actions to ensure these requirements were performed by them. It is foreseeable that Plaintiffs would be injured by the failure of the Defendants to perform these duties, and these Defendants had actual knowledge that the failure of these duties was causing harm to states, counties, and municipalities-like Plaintiffs.

The Retail Defendants further owed Plaintiffs a duty to refrain from, and enact policies to prevent, filling opioid prescriptions that would be deemed questionable or suspicious by a reasonably prudent pharmacist; a duty to train and supervise their employees at the point of sale to investigate or report suspicious or invalid prescriptions; a duty to check the state prescription monitoring program before dispensing prescriptions; and a duty to protect against corruption or theft by their employees or agents. The Retail Defendants had control over their own actions to ensure these requirements were performed by them. It is foreseeable that Plaintiffs would be injured by the failure of the Defendants to perform these duties, and these Defendants had actual knowledge that the failure of these duties was causing harm to states, counties, and municipalities like Plaintiffs.

385. The Physician Defendants further owed Plaintiffs a duty to, at the very least, refrain from prescribing or dispensing opioids for the purpose of maintaining patients' addiction or diversion to the illicit market.

386. Defendants' conduct fell below the reasonable standard of care. Their negligent acts include:

- a. consciously oversupplying the market throughout the State with highly-addictive prescription opioids;
- b. using unsafe distribution and dispensing practices;
- c. disregarding the Arkansas statutes and regulations for safe dispensing;
- d. affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;
- e. inviting and enabling criminal activity in the State, counties, and cities by disregarding precautionary measures built into Arkansas law;
- f. failing to properly train or investigate their employees;
- g. failing to properly review controlled substance orders for red flags;
- h. failing to establish effective controls to combat diversion of opioids;
- i. failing to police the integrity of their supply chains;

- j. knowingly writing illegitimate opioid prescriptions to feed addiction; and
- k. knowingly writing illegitimate opioid prescriptions for diversion to the illicit market.

387. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

388. Each Defendant sold opioids in the supply chain knowing both that (1) there was a substantial likelihood many of the sales were for non-medical purposes, and (2) opioids are an inherently dangerous product when used for non-medical purposes.

389. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

390. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

391. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of: corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

392. Defendants are in a limited class of registrants authorized to legally manufacture and distribute controlled substances. Likewise, Defendants are in exclusive control of the management of the opioids they distributed to retail stores throughout Arkansas. This places Defendants in a position of great trust and responsibility vis-à-vis the Plaintiffs. Defendants owe a special duty to the Plaintiffs; the duty owed cannot be delegated to another party.

393. The Plaintiffs are without fault, and their injuries and those of their citizens would not have happened in the ordinary course of events had the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

394. The aforementioned conduct of Defendants foreseeably and proximately caused damage to the Plaintiffs, which have suffered an unprecedented epidemic of opioid addiction and overdose.

395. As a result of the epidemic, the Plaintiffs have shouldered tremendous costs that are not derivative of third-party injuries. Plaintiffs' damages include, but are not limited to, increased emergency response costs, law enforcement costs, incarceration costs, court administration costs, addiction treatment costs, and medical costs caused by Defendants' conduct in creating and exacerbating the opioid epidemic. High levels of sustained opioid drug abuse, also created or accelerated economic blight in some portion of the State of Arkansas and Plaintiff Counties and Cities, resulting in diminished property values and a loss in tax revenue. The Plaintiffs have also suffered a loss of productivity in their workforces.

396. The opioid epidemic has caused the Plaintiffs to suffer past, present, and future damages in the form of the increased expenses in providing public services that so far exceed the normal, expected costs that they are distinct from and unrelated to the normal provision of public services. Defendants' conduct was extraordinary, unexpected, and rare, and is a repeated course of conduct that did, does, and will continue to result in recurring costs to the Plaintiffs. The magnitude of the acts of the Defendants were neither discrete nor of a sort that a state, county, or municipality, including the Plaintiffs, could reasonably expect to have to respond to at any time during their existence as such. It would be unreasonable, wrong, and inequitable not to allocate these additional governmental expenses, and any other costs associated with the harms

Defendants' wrongful conduct has caused, to the very parties responsible for creating the need for such extraordinary resources to be expended in the manner they were—and will be—in responding to the opioid epidemic.

397. As a direct result of Defendants' grossly negligent, willful, wanton, reckless, malicious, and/or intentional conduct, Plaintiffs have suffered actual injury entitling them to an award of all compensatory damages incurred in the past and likely to occur in the future, and punitive damages.

**COUNT II**  
**Common Law Public Nuisance**  
**(Against All Defendants)**

398. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

399. The nuisance is the over-saturation of opioids in the Plaintiffs' cities and counties for non-medical purposes, the adverse social and environmental outcomes associated with widespread illegal opioid use, and the attendant endangerment of public health, welfare, and safety.

400. All Defendants substantially participated in and/or aided and abetted activities that caused the nuisance.

401. Defendants caused the nuisance by selling or facilitating the sale of prescription opioids from premises in and around the Plaintiffs' cities and counties to unintended users—including children, people at risk of overdose or suicide, and criminals.

402. Defendants also caused the nuisance by failing to implement effective controls and procedures in their supply chain to guard against theft, diversion, and misuse of controlled substances.

403. The Defendants had actual knowledge that the conditions created by their actions and inactions as described herein would in fact and did result in harm to the Plaintiffs:

404. The Defendants were driven by profits and had the intent to over-saturate the market with opioids and cause addiction in order to boost sales.

405. The Defendants were further aware and complicit in their knowledge that their failure to follow state law would remove them from any regulated scheme of commerce of opioids.

406. Defendants' activities unreasonably interfere with the following common rights of the public, including the Plaintiffs' citizens:

- a. to be free from reasonable apprehension of danger to person and property;
- b. to be free from the spread of disease within the community including the disease of addiction and other diseases associated with widespread illegal opioid use;
- c. to be free from negative health and safety effects of widespread illegal drug sales on premises in and around the State of Arkansas and Plaintiff Counties and Cities;
- d. to be free from blights on the community created by areas of illegal drug use and opioid sales;
- e. to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and,
- f. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

407. The Defendants' interference with these public rights is unreasonable because it:

- a. has harmed and will continue to harm the public health, safety, and welfare of the Plaintiffs' citizens;
- b. has harmed and will continue to harm Plaintiffs' neighborhoods and communities by increasing the levels of vagrancy and property crime, and thereby interfering with the rights of the community at large;
- c. is proscribed by Arkansas statutes, including the Arkansas Controlled Substances Act and Uniform Narcotic Drug Act;
- d. is proscribed by Arkansas regulations, including those of the Department of Health and the Pharmacy Board; and
- e. is of a continuing nature, and will produce long-lasting effects.

408. The nuisance undermines the Plaintiffs' citizens' public health, safety, and welfare. It has resulted in increased crime and property damage within the Plaintiffs' cities and counties. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within the Plaintiffs' families and entire communities, which threatens the fabric of the Plaintiffs' society.

409. Public resources are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources which could be used to benefit the Plaintiffs' public at large.

410. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately-recognized societal interest in deceptively marketing opioids, misrepresenting the risks and benefits of opioids, or failing to maintain effective controls against opioid diversion.

411. At all times, all Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale into the Plaintiffs' cities and counties.

412. As a direct and proximate result of the nuisance, the Plaintiffs' citizens have suffered in their ability to enjoy the rights of the public.

413. As a direct and proximate result of the nuisance, the Plaintiffs have sustained economic harm by spending a substantial amount of money trying to fix the societal harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services, rehabilitation services, prisons and jails, courts, and law enforcement.

414. The Plaintiffs have also suffered unique harms of a kind that is different from the Plaintiffs' citizens at large, namely, that the Plaintiffs have been harmed in each's proprietary interests.

415. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

416. As a direct result of Defendants' grossly negligent, willful, wanton, reckless, malicious, and/or intentional conduct, Plaintiffs have suffered actual injury entitling them to an award of all compensatory damages incurred in the past and likely to occur in the future, and punitive damages.

417. Defendants should be required to pay the expenses the Plaintiffs have incurred or will incur in the future to fully abate the nuisance, as well as punitive damages.

### COUNT III

**Violations of the Arkansas Uniform Narcotic Drug Act,  
ARK. CODE ANN. §§ 20-64-101, *et seq.*:  
Civil Action by Crime Victim, ARK. CODE ANN. § 16-118-107  
(Against All Defendants)**

418. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

419. ARK. CODE ANN. § 16-118-107 provides that "[a]ny person injured or damaged by reason of conduct of another person that would constitute a felony under Arkansas law may file a civil action to recover damages based on the conduct."

420. The Arkansas Uniform Narcotic Drug Act ("UNDA") states, "It shall be unlawful for any person to manufacture, purchase, possess, have under his control, sell, prescribe, administer, dispense, or compound any narcotic drug, *except as authorized by this subchapter.*" ARK. CODE ANN. § 20-64-202 (emphasis added).

421. "Narcotic drug[s]" are those that are "promotive of addiction-forming or addiction-sustaining results upon the user which threaten harm to the public health, safety, or morals . . . whether produced directly or indirectly by extraction from substances of vegetable origin or



independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.” ARK. CODE ANN. § 20-64-201(8).

422. Any violation of the UNDA constitutes a felony. ARK. CODE ANN. § 20-64-220.

423. The UNDA empowers the Arkansas Department of Health to “promulgate regulations for the efficient enforcement of th[e] act. . . .” ARK. CODE ANN. § 20-64-419. The Department has done so in its regulations under Division 7, Rule 2. *See* ARK. ADMIN. CODE §§ 007.07.2-I-I.

424. Under authority of the UNDA, the Department mandates that “[a]ll Practitioners shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” ARK. ADMIN. CODE § 007.07.2-II-III. “Practitioners” include physicians, pharmacies, manufacturers, wholesalers, and distributors—i.e., all Defendants. *Id.* § 007.07.2-II-I.

425. Department of Health regulations further mandate that opioid prescriptions issue only for legitimate medical purposes. ARK. ADMIN. CODE § 007.07.2-II-VIIB(1). Any physician or pharmacist who knowingly prescribes or dispenses a controlled substance for illegitimate purposes—that is, to “an addict or habitual user” to “keep him/her comfortable by maintaining his/her customary use”—commits a felony. *Id.* § 007.07.2-II-VIIB(2).

426. As described throughout this Complaint, Defendants have violated the UNDA by, *inter alia*:

- a. consciously oversupplying the market throughout Arkansas with highly-addictive prescription opioids;
- b. using unsafe distribution and dispensing practices;
- c. disregarding statutory and regulatory rules for safe distributing and dispensing;
- d. affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

- e. inviting and enabling criminal activity in the State, counties, and cities by disregarding precautionary measures built into Arkansas law;
- f. failing to properly train or investigate their employees;
- g. failing to properly review controlled substance orders for red flags;
- h. failing to establish effective controls to combat diversion of opioids;
- i. failing to police the integrity of their supply chains;
- j. knowingly prescribing opioids for illegitimate purposes; and
- k. knowingly dispensing opioids for illegitimate purposes.

427. As a direct result of the Defendants' negligent, grossly negligent, knowing, willful, wanton, reckless, and/or intentional violations of the UNDA, the Plaintiffs have suffered actual injury entitling them to an award of all compensatory damages incurred in the past and likely to occur in the future, and punitive damages.

#### COUNT IV

#### **Accomplice to Violations of the Arkansas Uniform Narcotic Drug Act,**

**ARK. CODE ANN. §§ 5-2-403; 20-64-101, *et seq.*:**

**Civil Action by Crime Victim, ARK. CODE ANN. § 16-118-107**

**(Against All Defendants)**

428. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

429. ARK. CODE ANN. § 16-118-107 provides that "[a]ny person injured or damaged by reason of conduct of another person that would constitute a felony under Arkansas law may file a civil action to recover damages based on the conduct."

430. ARK. CODE ANN. § 5-2-403(a) provides that "[a] person is an accomplice of another person in the commission of an offense if, with the purpose of promoting or facilitating the commission of an offense, the person: (1) [s]olicits, advises, encourages, or coerces the other person to commit the offense; (2) [a]ids, agrees to aid, or attempts to aid the other person in

planning or committing the offense; or (3) [h]aving a legal duty to prevent the commission of the offense, fails to make a proper effort to prevent the commission of the offense.”

431. As set out above, Defendants manufactured, distributed, dispensed, and prescribed opioids in violation of the Arkansas UNDA and accompanying Arkansas Department of Health regulations. Defendants’ unauthorized manufacture, distribution, dispensing, and prescribing constitute felonies under the UNDA.

432. To maximize profits, Defendants manufactured, encouraged excessive prescriptions, distributed, and dispensed as many highly-addictive, and often deadly, pills as possible. To that end, Defendants transferred pills through the supply chain, from the manufacturer to the end user, and without regard for state law requiring them to take affirmative steps to prevent the diversion of drugs into the illegal marketplace or for other illegitimate purposes.

433. The Manufacturer Defendants continuously supplied opioids to Distributor Defendants despite knowing that Distributor Defendants were habitually violating state law, despite knowing of widespread opioid diversion and abuse, and despite Manufacturer Defendants’ duty to prevent diversion. The Distributor Defendants, in turn, continuously supplied opioids to Retail Defendants, despite Distributor Defendants’ knowledge that the Retail Defendants were habitually violating state law in dispensing opioids, despite knowing of widespread opioid diversion and abuse, and despite Distributor Defendants’ duty to prevent diversion.

434. The Retail Defendants and other retail stores continuously paid the Distributor Defendants to supply large quantities of prescription opioids and continuously dispensed them in order to satisfy demand for the drugs, despite knowing of their illegitimate or, at best, suspicious nature, despite knowing that Manufacturer Defendants and Distributor Defendants were habitually violating state law, and despite Retail Defendants’ duty to prevent diversion.

435. Thus, Defendants actively aided in, agreed to aid in, and failed to prevent each other and other manufacturers, distributors, retail stores, and physicians from habitually violating the Arkansas UNDA and Department of Health regulations, and Defendants failed to prevent each other from engaging in or aiding others' opioid diversion, despite Defendants' duty to do so.

436. As a direct result of the Defendants' knowing, willful, wanton, reckless, and/or intentional conduct, the Plaintiffs have suffered actual injury entitling them to an award of all compensatory damages incurred in the past and likely to occur in the future, and punitive damages.

#### COUNT V

#### **Civil Conspiracy to Violate the Arkansas Uniform Narcotic Drug Act (Against All Defendants)**

437. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

438. The Defendants, along with other manufacturers, wholesale distributors, retail stores, and physicians, agreed to continuously oversupply prescription opioids without regard for the drug's end use and without regard for the UNDA requiring them to guard against opioid diversion.

439. Disregarding their statutory and regulatory duties to guard against diversion, Defendants are not concerned with consumers' opioid use after sale. Consumers may ingest the opioids for purportedly legitimate medical purposes, such as to treat severe acute or chronic pain; they may abuse the opioids personally by ingesting them for recreational purposes or to feed a drug addiction; or they may give or sell them to a third party abuser who ingests them recreationally or to feed an addiction.

440. The Defendants' goal was to maximize their profits at all costs—to manufacture, encourage excessive prescriptions, distribute, and sell as many highly addictive, and often deadly, pills as possible. The Defendants accomplished this by transferring pills through the supply chain,

from the manufacturer to the end user, and without regard for the UNDA requiring them to take affirmative steps to prevent the diversion of drugs into the illegal marketplace or other illegitimate purposes.

441. The Manufacturer Defendants continuously supplied opioids to Distributor Defendants and other wholesale distributors despite knowing that the Distributor Defendants and other wholesale distributors were habitually breaching their common law duties and violating state law. The Distributor Defendants, in turn, continuously supplied opioids to Retail Defendants and other retail stores, despite the Manufacturer Defendants' and Distributor Defendants' knowledge that the Retail Defendants and other retail stores were habitually breaching their common law duties and violating state law in dispensing opioids.

442. Without the Defendants' supply of opioids, the Retail Defendants and other retail stores would not be able to fill and dispense the increasing number of prescription opioids throughout the Plaintiffs' cities and counties.

443. The Retail Defendants and other retail stores continuously paid the Distributor Defendants to supply large quantities of prescription opioids and continuously dispensed them in order to satisfy demand for the drugs, regardless of their suspicious nature.

444. To achieve their goal, these Defendants systematically violated their statutory duties to maintain effective controls against opioid diversion for illegitimate purposes.

445. Defendants knew that opioid diversion would endanger public health, welfare, or safety.

446. As a direct result of the Defendants' knowing, willful, wanton, reckless, and/or intentional concerted action, the Plaintiffs have suffered actual injury entitling them to an award

of all compensatory damages incurred in the past and likely to occur in the future, and punitive damages.

#### **COUNT VI**

**Possessing, Delivering, Manufacturing, and Trafficking Controlled Substances  
in Violation of the Arkansas Controlled Substances Act,  
ARK. CODE ANN. §§ 5-64-419, 5-64-424, 5-64-426, 5-64-427, and 5-64-440:  
Civil Action by Crime Victim, ARK. CODE ANN. § 16-118-107  
(Against All Defendants)**

447. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

448. ARK. CODE ANN. § 16-118-107 provides that “[a]ny person injured or damaged by reason of conduct of another person that would constitute a felony under Arkansas law may file a civil action to recover damages based on the conduct.”

449. The Arkansas CSA directs the Arkansas Department of Health to classify certain substances that have “high potential for abuse” and “may lead to severe psychic or physical dependence” as Schedule II controlled substances. ARK. CODE ANN. § 5-64-205. Schedule II controlled substances include codeine, hydrocodone, hydromorphone, morphine, oxycodone, oxymorphone, tapentadol, dihydrocodeine, fentanyl, methadone, and pethidine (meperidine). ARK. ADMIN. CODE § 007.02.2.

450. As discussed more fully above, the Arkansas CSA and accompanying Department of Health regulations permit the Manufacturer Defendants, Distributor Defendants, and Retail Defendants to manufacture, distribute, and dispense controlled substances within Arkansas subject to their compliance with the Arkansas CSA and Department of Health regulations. Outside the bounds set by state law, possessing, delivering, manufacturing, and trafficking in controlled substances is unlawful.

451. ARK. CODE ANN. § 5-64-419 provides that, except as authorized by the Arkansas CSA, it is unlawful to possess a Schedule II controlled substance. Such possession is a felony. *Id.*

452. ARK. CODE ANN. § 5-64-424 provides that, except as authorized by the Arkansas CSA, it is unlawful to possess a Schedule II controlled substance with purpose to deliver. Such possession with purpose to deliver is a felony. *Id.*

453. ARK. CODE ANN. § 5-64-426 provides that, except as authorized by the Arkansas CSA, it is unlawful to deliver a Schedule II controlled substance. Such delivery is a felony. *Id.*

454. ARK. CODE ANN. § 5-64-427 provides that, except as authorized by the Arkansas CSA, it is unlawful to manufacture a Schedule II controlled substance. Such manufacture is a felony. *Id.*

455. ARK. CODE ANN. § 5-64-440 provides that, except as authorized by the Arkansas CSA, it is unlawful to traffic a Schedule II controlled substance. Such trafficking is a felony. *Id.*

456. As discussed above, the Manufacturer Defendants, Distributor Defendants, and Retail Defendants unlawfully possessed, delivered, manufactured, and trafficked controlled substances in Arkansas while knowingly ignoring their statutory and regulatory duties to, *inter alia*, maintain effective controls against opioid diversion.

457. As a direct result of the Defendants' negligent, grossly negligent, knowing, willful, wanton, reckless, and/or intentional violations of the CSA, the Plaintiffs have suffered actual injury entitling them to an award of all compensatory damages incurred in the past and likely to occur in the future, and punitive damages.

#### COUNT VII

Accomplice to Violations of the Arkansas Controlled Substances Act,  
ARK. CODE ANN. §§ 5-64-419, 5-64-424, 5-64-426, 5-64-427, and 5-64-440:  
Civil Action by Crime Victim, ARK. CODE ANN. § 16-118-107  
(Against All Defendants)

458. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

459. ARK. CODE ANN. § 16-118-107 provides that “[a]ny person injured or damaged by reason of conduct of another person that would constitute a felony under Arkansas law may file a civil action to recover damages based on the conduct.”

460. ARK. CODE ANN. § 5-2-403(a) provides that “[a] person is an accomplice of another person in the commission of an offense if, with the purpose of promoting or facilitating the commission of an offense, the person: (1) [s]olicits, advises, encourages, or coerces the other person to commit the offense; (2) [a]ids, agrees to aid, or attempts to aid the other person in planning or committing the offense; or (3) [h]aving a legal duty to prevent the commission of the offense, fails to make a proper effort to prevent the commission of the offense.”

461. As set out above, Defendants unlawfully manufactured, possessed, delivered, and trafficked prescription opioids in violation of the Arkansas CSA and accompanying Department of Health regulations. Defendants’ manufacture, possession, delivery, and trafficking constitute felonies under Arkansas law.

462. To maximize profits, Defendants manufactured, encouraged excessive prescriptions, distributed, and dispensed as many highly-addictive, and often deadly, pills as possible. To that end, Defendants transferred pills through the supply chain, from the manufacturer to the end user, and without regard for state law requiring them to take affirmative steps to prevent the diversion of drugs into the illegal marketplace or for other illegitimate purposes.

463. The Manufacturer Defendants continuously supplied opioids to Distributor Defendants despite knowing that Distributor Defendants were habitually violating state law, despite knowing of widespread opioid diversion and abuse, and despite Manufacturer Defendants’



duty to prevent diversion. The Distributor Defendants, in turn, continuously supplied opioids to Retail Defendants and other retail stores, despite Distributor Defendants' knowledge that the Retail Defendants and other retail stores were habitually violating state law in dispensing opioids, despite knowing of widespread opioid diversion and abuse, and despite Distributor Defendants' duty to prevent diversion.

464. The Retail Defendants and other retail stores continuously paid the Distributor Defendants to supply large quantities of prescription opioids and continuously dispensed them in order to satisfy demand for the drugs, despite knowing of their illegitimate or, at best, suspicious nature, despite knowing that Manufacturer Defendants and Distributor Defendants were habitually violating state law, and despite Retail Defendants' duty to prevent diversion.

465. Thus, Defendants actively aided in, agreed to aid in, and failed to prevent each other and other manufacturers, distributors, retail stores, and physicians from habitually violating the Arkansas CSA and Department of Health regulations, and Defendants failed to prevent each other from engaging in or aiding others' opioid diversion, despite Defendants' duty to do so.

466. As a direct result of the Defendants' knowing, willful, wanton, reckless, and/or intentional conduct, the Plaintiffs have suffered actual injury entitling them to an award of all compensatory damages incurred in the past and likely to occur in the future, and punitive damages.

#### COUNT VIII

#### **Civil Conspiracy to Violate the Arkansas Controlled Substances Act (Against All Defendants)**

467. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

468. The Defendants, along with other wholesale distributors, retail stores, and physicians, agreed to continuously oversupply prescription opioids without regard for the drugs' end use and without regard for state law requiring them to guard against opioid diversion.

469. Disregarding their statutory and regulatory duties to guard against diversion, Defendants are not concerned with consumers' opioid use after sale. Consumers may ingest the opioids for purportedly legitimate medical purposes, such as to treat severe acute or chronic pain; they may abuse the opioids personally by ingesting them for recreational purposes or to feed a drug addiction; or they may give or sell them to a third party abuser who ingests them recreationally or to feed an addiction.

470. The Defendants' goal was to maximize their profits at all costs—to manufacture, encourage excessive prescriptions, distribute, and sell as many highly addictive, and often deadly, pills as possible. The Defendants accomplished this by transferring pills through the supply chain, from the manufacturer to the end user, and without regard for state law requiring them to take affirmative steps to prevent the diversion of drugs into the illegal marketplace or for other illegitimate purposes.

471. The Manufacturer Defendants continuously supplied opioids to Distributor Defendants and other wholesale distributors despite knowing that the Distributor Defendants and other wholesale distributors were habitually breaching their common law duties and violating state law. The Distributor Defendants, in turn, continuously supplied opioids to Retail Defendants and other retail stores, despite the Manufacturer Defendants' and Distributor Defendants' knowledge that the Retail Defendants and other retail stores were habitually breaching their common law duties and violating state law in dispensing opioids.

472. Without the Defendants' supply of opioids, the Retail Defendants and other retail stores would not be able to fill and dispense the increasing number of prescription opioids throughout the Plaintiffs' cities and counties.

473. The Retail Defendants and other retail stores continuously paid the Distributor Defendants to supply large quantities of prescription opioids and continuously dispensed them in order to satisfy demand for the drugs, regardless of their suspicious nature.

474. To achieve their goal, these Defendants systematically violated their statutory and regulatory duties to, *inter alia*, maintain effective controls against opioid diversion.

475. Defendants knew that opioid diversion would endanger public health, welfare, or safety.

476. As a direct result of the knowing, willful, wanton, reckless, and/or intentional concerted action between the Defendants, the Plaintiffs have suffered actual injury entitling them to an award of all compensatory damages incurred in the past and likely to occur in the future, and punitive damages.

**COUNT IX**  
**Violations of the Arkansas Drug Dealer Liability Act,**  
**ARK. CODE ANN. §§ 16-124-101, *et seq.***  
**(Against All Defendants)**

477. The Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully stated herein.

478. The Arkansas Drug Dealer Liability Act ("DDLA") provides a civil remedy "for damages caused by use of an illegal drug by an individual." ARK. CODE ANN. § 16-124-104(a).

479. An "illegal drug" is any "drug whose distribution is a violation of the Uniform Controlled Substances Act." ARK. CODE ANN. § 16-124-102(1). Thus, opioids that Defendants' manufactured, possessed, delivered, trafficked, dispensed, or prescribed in violation of the Arkansas CSA and accompanying Department of Health regulations constitute "illegal drugs" under the DDLA.

480. The DDLA's remedies extend to "a medical facility, insurer, governmental entity, employer, or other entity that funds a drug treatment program or employee assistance program for the individual drug user, or that otherwise expended money on behalf of the individual drug user." ARK. CODE ANN. § 16-124-104(a)(4).

481. Plaintiffs are governmental entities that fund drug treatment programs or have otherwise expended, and will continue to expend, money on behalf of illegal drug users. Indeed, prescription opioid diversion and the corresponding increase in abuse, addiction, and criminal activity has placed an **insurmountable demand** on County and City resources to meet the medical, public health, jail and prison, court, and law enforcement needs of their communities.

482. Under the DDLA, any "person who knowingly participates in the illegal drug market is liable for civil damages," ARK. CODE ANN. § 16-124-103(b), and the "illegal drug market" extends "from production to retail sales." *Id.* § 16-124-102(2).

483. The DDLA imposes liability on those who directly participate in the distribution of an illegal drug that causes damage. This includes any "person who knowingly distributed, or knowingly participated in the chain of distribution of, an illegal drug that was actually used by the individual drug user." ARK. CODE ANN. § 16-124-104(b)(1).

484. It also imposes market liability on those who participate in the illegal drug distribution in the area where the illegal drug causes damage. This includes any "person who knowingly participated in the illegal drug market if: (A) [t]he place of the illegal drug activity by the individual drug user is within the illegal drug market target community of the defendant; (B) [t]he participation of the defendant in the illegal drug market was connected with the same type of illegal drug used by the individual drug user; and (C) [t]he defendant participated in the illegal

drug market at any time during the illegal drug use of the individual drug user.” ARK. CODE ANN. § 16-124-104(b)(2).

485. An individual drug user is “the individual whose illegal drug use is the basis of an action brought under” the DDLA. ARK. CODE ANN. § 16-124-102(4). Plaintiffs’ residents who purchased or used Schedule II prescription opioids without valid and/or effective prescriptions are “individual drug users” under the DDLA.

486. Defendants knowingly participated in the manufacture, distribution, and dispensing of prescription opioids that reached the Plaintiffs during all times relevant to this Complaint. Defendants’ “illegal drug market target community” is the entire State of Arkansas, because Defendants participated in the illegal drug market by distributing four or more ounces of “specified illegal drug[s],” that is, Schedule II controlled substances. ARK. CODE ANN. §§ 16-124-102(5), (14); 16-124-109(4).

487. The Manufacturer Defendants and Distributor Defendants knowingly failed to implement effective controls and procedures in their supply chains to guard against theft, diversion, and abuse of prescription opioids in violation of the Arkansas CSA and Department of Health regulations.

488. As a result, the Manufacturer Defendants and Distributor Defendants knowingly supplied massive quantities of prescription opioids to suspect physicians and pharmacies and into the illicit market, including diversion enterprises such as KJ Medical Clinic, Dr. Brooks, Dr. Reifeiss, and Bowman Curve Pharmacy; Perry County Food & Drug; Dr. Ahmad, UPC, and Linden Care; Dr. Johns; and other diversion operations.

489. The Manufacturer Defendants and Distributor Defendants knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the illicit market, including

diversion enterprises such as KJ Medical Clinic and Bowman Curve Pharmacy; Perry County Food & Drug; Dr. Ahmad, UPC, and Linden Care; Dr. Johns; and other diversion operations, knowing that such opioids would be illegally diverted and abused.

490. As a direct result of Defendants' knowing and/or intentional conduct, the Plaintiffs have suffered actual injury entitling them to an award of all damages available under the DDLA that they have incurred in the past and are likely to incur in the future, including punitive damages.

#### VII. JOINT AND SEVERAL LIABILITY

491. This case arises from a nationwide effort among opioid manufacturers to first manipulate public and professional perception of opioids—even then (and for a century or more before then) commonly known as dangerous and highly-addictive. Once they achieved this shift in longstanding public and professional disposition, the same manufacturers then acted in concert with wholesale distributors and retail stores to continuously saturate the market with these drugs to make colossal profits, even in the wake of known widespread abuse, addiction, overdose, death, and criminal activity.

492. *At a minimum*, all Defendants knowingly aided and abetted even the worst conduct of the most culpable Defendants and profited from their illegal conduct at the expense of the Plaintiffs and their citizens.

493. Defendants acted in concert, and in doing so, are jointly and severally liable to Plaintiffs for the claims at issue in this Complaint.

#### PRAYER FOR RELIEF

Despite the best efforts of the State, Counties, and Cities, through an allocation of all available resources, the Arkansas Opioid Epidemic continues to infect Arkansas. Absent the relief sought in this action, the resources of the State, Counties, and Cities will continue to be inadequate to respond to the epidemic.

WHEREFORE, Plaintiffs respectfully pray:

A. That Plaintiffs recover all measures of damages allowable, and that judgment be entered against Defendants in favor of Plaintiffs and for those damages to include, but not be limited to:

1. Past damages and restitution for monies spent by the State, Counties, and Cities for those extraordinary and additional services provided which they would not have otherwise incurred but as a result of the Arkansas Opioid Epidemic and their past efforts to abate it.
2. Prospective damages so that the State, Counties, and Cities can **comprehensively intervene in the Arkansas Opioid Epidemic:**
  - a. to **prevent opioid use, injury, and death** through, *inter alia*, the purchase of naloxone kits for drug users, first responders, jailers, hospitals, schools, public buildings, and other appropriate recipients; and requisite training in the identification of overdose and proper naloxone administration;
  - b. to **treat, cure, and prevent opioid misuse and addiction** through, *inter alia*, the creation of mental health clinics, opioid abuse treatment clinics, programs to increase public awareness of opioid addiction, programs to remove barriers to treatment and insurance coverage, and programs to increase physician awareness of opioid addiction and to correct misinformation disseminated by Defendants directly or through KOLs, Front Groups, and other third parties; connecting Arkansas citizens to effective treatment, including medication-assisted treatment and telemedicine; and creating and disseminating educational materials for elementary schools, high schools, vocational schools, colleges and universities;
  - c. to **reduce the supply of dangerous opioids** through, *inter alia*, testing and information-sharing so that law enforcement can better understand the Arkansas Opioid Epidemic; creating overdose response teams; hiring and training of additional patrol officers and detectives, hiring and training of additional lab personnel, and hiring and training of additional personnel to optimize the Arkansas Prescription Monitoring Program; expanding efforts to provide clear guidance on safe disposal of prescription opioids; expanding take-back programs; creating linked and shared public health, healthcare, and criminal justice data related to the Arkansas Opioid Epidemic; and
  - d. To **reduce crime and involuntary commitments associated with opioid addiction** through, *inter alia*, creating and expanding drug and mental health courts in the Arkansas judicial system; crisis stabilization units;

treatment options in jails and prisons; training of law enforcement, first responders, jailers, and other regarding crisis intervention and diversion; and prisoner re-entry programs;

B. That Plaintiffs recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law;

C. That Defendants be ordered to pay punitive and treble damages as provided by law; and;

D. That the Court order such other and further relief as the Court deems just, necessary and appropriate.



JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all claims to the maximum number of jurors permitted by law.

Respectfully submitted,

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STATE OF ARKANSAS, et al.  
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02

**COVER SHEET**  
**STATE OF ARKANSAS**  
**CIRCUIT COURT: CIVIL**

*Additional Civil Case Party Information. Attach this and additional pages if needed.*

If amending an existing case to add parties, include:

Case ID: \_\_\_\_\_

Case Styling: State of AR, ex rel., Scott Ellington, 2nd Judicial Circuit Prosecuting Attorney et al.  
 v. Purdue Pharma, L.P., et al.

|                        |  |                        |  |
|------------------------|--|------------------------|--|
| <b>Party type:</b>     | <input checked="" type="radio"/> Plaintiff <input type="radio"/> Defendant         | <b>Party type:</b>     | <input checked="" type="radio"/> Plaintiff <input type="radio"/> Defendant         |
| Company/<br>Last Name  | County of Pulaski, Arkansas  | Company/<br>Last Name  | County of Jefferson, Arkansas  |
| Suffix                 |  | Suffix                 |  |
| First Name             |  | First Name             |  |
| DL/State ID            |  | DL/State ID            |  |
| Address                |  | Address                |  |
| City, State ZIP        |  | City, State ZIP        |  |
| Phone                  |  | Phone                  |  |
| Email                  |  | Email                  |  |
| Self-represented       | <input type="radio"/> Yes <input type="radio"/> No                                 | Self-represented       | <input type="radio"/> Yes <input type="radio"/> No                                 |
| DOB                    |  | DOB                    |  |
| Interpreter<br>needed? | <input type="radio"/> Yes: _____<br><input type="radio"/> No other language: _____ | Interpreter<br>needed? | <input type="radio"/> Yes: _____<br><input type="radio"/> No other language: _____ |

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| <b>Party type:</b>     | <input checked="" type="radio"/> Plaintiff <input type="radio"/> Defendant         | <b>Party type:</b>     | <input checked="" type="radio"/> Plaintiff <input type="radio"/> Defendant         |
| Company/<br>Last Name  |  | Company/<br>Last Name  |  |
| Suffix                 |  | Suffix                 |  |
| First Name             |  | First Name             |  |
| DL/State ID            |  | DL/State ID            |  |
| Address                |  | Address                |  |
| City, State ZIP        |  | City, State ZIP        |  |
| Phone                  |  | Phone                  |  |
| Email                  |  | Email                  |  |
| Self-represented       | <input type="radio"/> Yes <input type="radio"/> No                                 | Self-represented       | <input type="radio"/> Yes <input type="radio"/> No                                 |
| DOB                    |  | DOB                    |  |
| Interpreter<br>needed? | <input type="radio"/> Yes: _____<br><input type="radio"/> No other language: _____ | Interpreter<br>needed? | <input type="radio"/> Yes: _____<br><input type="radio"/> No other language: _____ |

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01



## RAINWATER HOLT &amp; SEXTON, P.A.

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 479-271-2310

Also, Internet fax  
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 \* Missouri  
 \* Tennessee  
 \* Wisconsin  
 \* Texas

April 2, 2018

Via Facsimile: (870) 739-3287

Ms. Donna Palmer  
 Crittenden County Circuit Clerk  
 100 Court Street  
 Marion, Arkansas 72364

Re: *State of Arkansas, ex rel Scott Ellington,  
 Second Judicial Circuit Prosecuting Attorney, et al  
 v. Purdue Pharma, L.P.  
 Crittenden County Circuit Court, No. CV-2018-268*

Dear Ms. Palmer:

Attached please find the Civil Cover Sheet adding two additional parties that are named in the Second Amended Complaint which is being filed in your office.

Should you have any questions or need additional information regarding this matter, please contact my paralegal, Stacie Allen, at (501) 868-2992.

Thank you for your assistance in this matter.

Sincerely,

Stacie Allen

Stacie Allen

/sra

Attachments

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 2018 APR -2 PM 4:26  
 TERRY HARKINS  
 CIRCUIT COURT CLERK  
 CRITTENDEN COUNTY, AR

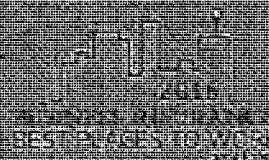
## **EXHIBIT D**





2017 POLICY

Thank you  
for being  
our policyholder





Pernix Therapeutics Holdings Inc.

PH17LGL0A78IVNV

11/30/2017 to 11/30/2018

RT Specialty, LLC





## COMPLIMENTARY CONSULTATION

Navigators has partnered with national law firm Wilson Elser to provide eligible policyholders\* with a one-hour consultation with an experienced attorney on a topic of their choice. As a Navigators Insurance Company Life Sciences policyholder, you have access to this complimentary service conducted by an experienced life sciences defense attorney.

Following are just a few of the topics you may consider for discussion when you take advantage of this consultative service, or you may select another area of interest.

### LIFE SCIENCES

- MedWatch reports (especially any causation analyses or manufacturer comments) prior to submission to the FDA.
- Labeling changes prior to submission to the FDA.
- Demand letters from potential litigants.
- Periodic safety report obligations prior to submission to the FDA.
- Correspondence received from the FDA and company obligations regarding response.
- Published peer-reviewed medical articles discussing off-label use of the insured's product and associated implications.
- Draft letters prior to submission to the FDA.
- Webinars related to e-Discovery.

### ALLIED HEALTHCARE

- Quality control and risk management.
- Operational issues such as reimbursement.
- Preparation of responses to subpoenas, records requests and government investigations.
- Provision and retention of medical records.
- Healthcare compliance and regulatory such as HIPAA.
- Protection from third-party liability/contractual indemnification.
- Use of arbitration as an alternate means of dispute resolution.
- Employment related and human resource issues such as EEOC claims and credentialing.

\*Per policy term of 12 months or longer

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**WILSON ELSE**  
WILSON ELSE MOSKOWITZ EDLMAN & DICKER LLP



For purposes of this consultation, your dedicated Wilson Elser attorneys will include:



#### Genese K. Dopson

Genese Dopson focuses her practice on the defense of Life Science companies. She has over 25 years experience in defending product liability and parallel claims asserted against pharmaceutical

and medical device manufacturers and she has a demonstrated track record of obtaining defense verdicts in jury trials. She has successfully managed the defense of multi-plaintiff, multi-state, litigation and she has been selected to serve as National Coordinating Counsel for medical device manufacturers as well as brand and generic pharmaceutical companies in mass tort litigation.

Leveraging her first career as a registered nurse, Genese brought her life science defense practice to Wilson Elser in 2009. She leads the firm's Life Sciences practice and coordinates efforts to field a nationwide team of creative, resolution-oriented attorneys in the Life Sciences arena.

[http://www.wilsonelser.com/attorneys/genese\\_k\\_dopson](http://www.wilsonelser.com/attorneys/genese_k_dopson)



#### Lori Semlies

Lori Semlies focuses on the defense of medical and nursing home malpractice claims in both state and federal courts, including all phases of litigation through trial.

As part of her risk management services for clients, Lori counsels staff on best practices in documentation in a medical institution. She also assists clients with drafting admission agreements and protocols and helps them manage crisis situations.

Co-chair of the firm's national Long Term Care Litigation Team, Lori has particular knowledge of state and federal regulations that pertain to long-term care facilities. Lori and the other members of the firm's nursing home team have developed useful strategies for getting claims dismissed and have crafted arguments for limiting the use of evidence during the liability phase of a trial. Lori is a much-sought-after speaker on best practices, using a mock examination of nursing staff to demonstrate the potential pitfalls of inadequate documentation.

[http://www.wilsonelser.com/attorneys/lori\\_r\\_semlies](http://www.wilsonelser.com/attorneys/lori_r_semlies)

To initiate your complimentary consultation, please call: 844-SCI-LIFE (844-724-5433).

#### ABOUT WILSON ELSE

Nearly 800 attorneys strong, our firm serves clients of all sizes, across multiple industries and around the world. Wilson Elser has 30 strategically located offices in the United States and one in London. This depth and scale has made us one of the nation's most influential law firms, ranked in the *Am. Law 200* and in the top 50 of the *National Law Journal 500*. Please visit us on the Web at [www.wilsonelser.com](http://www.wilsonelser.com).

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Wilson Elser has agreed to provide this consultation as a service to Navigators Insurance Company. By using this service, Navigators Life Sciences policyholders acknowledge that Wilson Elser is not their attorney and that no attorney-client relationship is created between Wilson Elser and the Navigators Life Sciences policyholders. By participating in a one-hour consultation with Wilson Elser, you understand that Wilson Elser is only offering pragmatic guidance and you agree that this forum is not intended to provide legal advice for a specific situation. If you require legal advice with respect to a specific legal matter, Wilson Elser reserves the right to referring an attorney-client relationship with you. This consultation is not a substitute for reporting a claim. To be eligible for coverage, claims must be reported using the procedures set forth in your insurance policy.

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## NAVIGATORS INSURANCE COMPANY

THIS POLICY PROVIDES COVERAGE ON A CLAIMS MADE BASIS.  
PLEASE READ THE ENTIRE POLICY CAREFULLY.

### DECLARATIONS

Attaching to and forming part of

#### NAVIGATORS GLOBAL LIFE SCIENCES GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE

IN RETURN FOR THE PAYMENT OF PREMIUM, AND SUBJECT TO ALL THE TERMS OF THIS POLICY, WE AGREE WITH YOU  
TO PROVIDE THE INSURANCE AS STATED IN THIS POLICY.

Policy Number: PH17LGL0A78IVNV

Producer Number: RTSP0008

Renewal of Policy Number: PH16LGL0A78IVNC

Insuring Company: Navigators Insurance Company  
One Penn Plaza  
New York, NY 10119

Producer: RT Specialty, LLC  
1515 Market Street, Suite 1110  
Philadelphia, PA 19103

1. First Named Insured: Pernix Therapeutics Holdings Inc.  
Address: 10 N Park Place, Ste 201  
Morristown, NJ 07960

2. Policy Period: From 11/30/2017 To 11/30/2018  
12:01AM STANDARD TIME AT THE ADDRESS SHOWN IN NUMBER 1 ABOVE.

3. Limits of Liability: Coverage - Products-Completed Operations Liability  
A. \$10,000,000 Each Claim - including Claims Expenses  
B. \$10,000,000 Aggregate - including Claims Expenses

4. Retroactive Date: See NAV LSC 009 01 16.  
THIS INSURANCE DOES NOT APPLY TO OCCURRENCES WHICH OCCUR BEFORE THE RETROACTIVE DATE.

5. Sublimits: Coverage - Mitigation Expenses Sub-limit - (included within the Limit of Liability and subject to 10% coinsurance participation):  
A. \$250,000 Each Claim or Circumstance - including Claims Expenses  
B. \$250,000 Aggregate - including Claims Expenses  
  
Coverage - Class 1 Product- Recall Expenses Sub-limit - (included within the Limit of Liability):  
A. \$250,000 Each Recall - including Claims Expenses  
B. \$250,000 Aggregate - including Claims Expenses  
  
Coverage - Medical Expenses Sub-limit - (in addition to the Limit of Liability):  
A. \$2,000 Each Person - including Claims Expenses  
B. \$20,000 Aggregate - including Claims Expenses

Coverage – Network Security Liability Sub-limit – (In addition to the Limit of Liability):

- A. \$ N/A Each Suit – Including Claims Expenses
- B. \$ N/A Aggregate – Including Claims Expenses

6. Deductible:

Coverage – Products-Completed Operations Liability

- A. \$250,000 Each Claim – including Claims Expenses
- B. \$1,250,000 Aggregate – including Claims Expenses

*(Treximet with respect to pediatric use and Cardiovascular Thrombotic, Heart Failure and Edema events; and Zohydro ER "1st generation without abuse deterrent technology")*

- A. \$100,000 Each Claim – including Claims Expenses
- B. \$500,000 Aggregate – including Claims Expenses

*(All other products, including Zohydro ER 2nd generation with abuse deterrent technology)*

Coverage – Class 1 Product- Recall Expenses Sub-limit

- A. \$10,000 Each Claim – including Claims Expenses
- B. \$ N/A Aggregate – Including Claims Expenses

Coverage – Network Security Liability Sub-limit

- A. \$ N/A Each Suit – including Claims Expenses
- B. \$ N/A Aggregate – including Claims Expenses

7. Premium:

\$500,345 Policy Term Premium, subject to Minimum Policy Premium

\$50,000 Minimum Policy Premium – Greater of \$50,000 or 25% of the premium above.  
(This applies even in the event of amendment of policy term)

Audit Rate: \$4.60 per \$1,000 of revenues in excess of audit basis

Audit Basis: \$124,000,000 (Any acquisitions during the policy period may be subject to additional underwriting consideration and additional premium)

8. Endorsements Attached At Issuance:

SEE ATTACHED SCHEDULE

By Acceptance of this policy the Insured agrees that the statements in the Declarations and the Application and any attachments hereto are the Insured's agreements and representations and that this policy embodies all agreements existing between the Insured and the Company or any of its representatives relating to this insurance.

IN WITNESS WHEREOF, we have caused this policy to be signed by our President and Secretary.

Stanley A. Galanski, President

Emily B. Miner, Secretary

**NAVIGATORS GLOBAL LIFE SCIENCES POLICY**  
**GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY INSURANCE FORM**

THIS POLICY PROVIDES COVERAGE ON A CLAIMS MADE BASIS.  
PLEASE READ THE ENTIRE POLICY CAREFULLY.

TABLE OF CONTENTS

|               |                                    |    |
|---------------|------------------------------------|----|
| Section I –   | Insuring Agreements                | 1  |
| Section II –  | Limits of Liability and Deductible | 2  |
| Section III – | Exclusions                         | 3  |
| Section IV –  | Definitions                        | 9  |
| Section V –   | Conditions                         | 20 |



**POLICY NUMBER: PH17LGL0A78IVNV**

**SCHEDULE OF FORMS AND ENDORSEMENTS  
GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE**

THE FOLLOWING ARE THE FORMS ATTACHED TO AND FORMING PART OF THE POLICY AT INCEPTION:

| Form Number     | Edition | Title  |
|-----------------|---------|--|
| NAV LSA DEC     | 07 17   | Declaration  |
| NAV LS 101      | 01 16   | Schedule of Forms and Endorsements                               |
| NAV LS 100      | 01 16   | GLS Elite Products-Completed Operations Liability Coverage Form  |
| NAV LS 103      | 07 16   | GLS Elite Plus Coverage Endorsement                              |
| NAV LSA 1000 NJ | 06 16   | New Jersey Amendatory Endorsement                                |
| NAV LS 102      | 07 16   | Designated Products Exclusion                                    |
| NAV LSC 004     | 01 16   | Specified Additional Insured Endorsement                         |
| NAV LSC 005     | 01 16   | Additional Named Insured Endorsement                             |
| NAV LSC 009     | 01 16   | Retroactive Date Schedule Endorsement                            |
| NAV LSU 414     | 12 16   | Pernix Therapeutics Holdings Inc. Manuscript Endorsement         |
| NAV LS 105      | 01 16   | Full Terrorism (Including Certified Acts of Terrorism) Exclusion |

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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**Navigators Life Sciences  
GLS Elite Products-Completed Operations Liability Coverage**

**THIS INSURANCE PROVIDES CLAIMS MADE COVERAGE  
PLEASE READ THE ENTIRE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES AND WHAT IS AND IS NOT  
COVERED**

Company means the insurer named in the Declarations. Other key words and phrases that appear in **bold type** have special meanings. Refer to Section IV. **DEFINITIONS**.

In consideration of the payment of the premium, and in reliance upon the information and statements provided in the **application and submission materials**, which are made a part of, deemed attached to, and incorporated into this Policy, with the understanding that any intentional material misrepresentation or omission made in the **application** may render this contract of insurance null and void and provide the Company with the right to rescind it, and subject to all the terms and conditions of this Policy, including without limitation, the Limits of Liability and Exclusions, it is agreed as follows:

**I. INSURING AGREEMENTS**

**A. Products-Completed Operations Hazard Coverage**

The Company will pay amounts in excess of the deductible or retention up to the limit of liability for **damages** that an **Insured** becomes legally liable to pay as a result of a **products-completed operations hazard claim**.

In addition, the Company will pay **claim expenses** in excess of the deductible or retention and up to the limit of liability in connection with a covered claim. **Claim expenses** are included within and erode both the limits of liability and the deductible or retention.

**B. When Coverage Applies**

This Policy applies to such claims under I. A. above only if:

1. such claim is both first made against an **Insured** during the **policy period** and reported in a timely manner to the Company in accordance with Section V. **CONDITIONS**, paragraph A. **Your Duties If There Is A Claim**;
2. prior to the effective date of the first Policy in our **coverage relationship**, no **executive officer** of the **Insured** seeking coverage knew of the **bodily injury, property damage or personal or advertising injury** giving rise to the claim;
3. prior to the effective date of the first Policy in our **coverage relationship**, the **Insured** seeking coverage did not give notice to a prior insurer of any **occurrence** giving rise to any such claim;
4. **your product, your work or the clinical trial** giving rise to such claim was first used, ingested, implanted, or applied, or first took place on or after the retroactive date specified in the Declarations; and
5. for **clinical trials**, the **Insured** seeking coverage has obtained all necessary authorizations prior to the **clinical trial(s)** starting and takes all reasonable steps to ensure each **clinical trial** is conducted within the scope of applicable protocols.

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**C. Defense**

**1. Duty to defend**

The Company has the right and duty to defend any covered claim, against an Insured, seeking damages that are payable under the terms of this Policy, even if any of the allegations of such claim are groundless, false or fraudulent. The Company will designate or, at its option, approve counsel to defend the claim.

If the law of the governing jurisdiction permits an Insured to select their own counsel to be paid for by the Company, we shall only be liable for the reasonable and necessary defense costs of one law firm per Insured at rates customarily paid for the defense of similar claims in the jurisdiction where the claim is pending

**2. Exhaustion of limits**

The Company is not obligated to investigate, defend, pay or settle, or continue to investigate, defend, pay or settle a claim after the applicable limit of the Company's liability has been exhausted by payment of damages or claim expenses or by any combination thereof. In such case, the Company shall have the right to withdraw from the further investigation, defense, payment or settlement of such claim by tendering control of said investigation, defense or settlement of the claim to the Insured.

**II. LIMITS OF LIABILITY AND DEDUCTIBLE OR RETENTION**

**A. Limit of Liability—Each Claim**

Subject to the provisions of II.B., below, the limit of liability of the Company for damages and claim expenses for each claim shall not exceed the amount stated in the Declarations for each claim.

If the Company, in the exercise of its discretion, pays any amount in excess of the applicable limit of liability, the Insured shall reimburse the Company for such amounts.

**B. Limit of Liability—Aggregate**

The limit of liability of the Company for damages and claim expenses for all claims shall not exceed the aggregate limit as set forth in the Declarations.

**C. Deductible or Retention**

1. The each claim deductible or retention shown in the Declarations applies to damages and claim expenses for each claim.
2. The aggregate deductible or retention shown in the Declarations applies to damages and claim expenses for all claims in the aggregate.

The limits of liability shown in the Declarations are in addition to and in excess of the deductible or retention.

If the Company, in the exercise of its discretion, pays any amount within the deductible or retention, the Insured shall reimburse the Company for such amounts.

**D. Multiple Insureds, Claims and Claimants**

The limits of liability shown in the Declarations are the amounts the Company will pay as damages or claim expenses regardless of the number of Insureds, claims made, or persons or entities making claims.

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If, during the policy period, a claim is made and if either you or the Company declares in writing to the other that such claim is likely to give rise to subsequent related claims, then such claim and all such subsequent related claims, shall be deemed a single claim. The limits of liability applicable to such single claim are the limits of liability in effect for the Policy in which the declaration was made.

**E. Claim Expenses Within the Limits**

Claim expenses are included within and erode the applicable limit of liability. Claim expenses with respect to a claim will be paid first and payment will reduce the amount available to pay damages.

**III. EXCLUSIONS**

This Policy does not apply to:

**A. Asbestos**

based on or arising out of:

1. the actual, alleged, suspected or threatened exposure at any time to asbestos or asbestos-containing products; or
2. any actual or alleged loss, cost or expense that may be awarded or incurred:
  - a. by reason of a claim for any such injury or damage; or
  - b. in complying with a governmental direction or request to test for, monitor, clean up, remove, contain or dispose of asbestos.

**B. Assumed Liability**

based on or arising out of any actual or alleged bodily injury or property damage for which any Insured is obligated to pay damages by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for damages:

1. for which an Insured would have been liable in the absence of the contract or agreement; or
2. assumed in a contract or agreement that is an insured contract, provided the bodily injury or property damage occurs subsequent to the execution of the contract or agreement. Solely for the purposes of liability assumed in an insured contract, reasonable attorney fees and necessary litigation expenses incurred by or for a party other than an Insured are deemed to be part of claim expenses because of bodily injury or property damage, provided:
  - a. liability to such party for, or for the cost of, that party's defense has also been assumed in the same insured contract; and
  - b. such attorney fees and litigation expenses are for defense of that party against a civil action or alternative dispute resolution proceeding in which damages to which this insurance applies are alleged.

**C. Banned Materials**

based on or arising out of your product or your work that is manufactured, developed, designed, created, tested, sold, leased, licensed, rented, handled, marketed, distributed or disposed of by you or others on your behalf in known violation of any law, statute, ordinance or regulation. For purposes of determining the applicability of this exclusion:

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1. the facts pertaining to and knowledge possessed by any natural person **Insured** shall not be imputed to any other natural person **Insured**; and
2. only facts pertaining to and knowledge possessed by any **Insured** as set forth in paragraph A. of the definition of **Insured** in **IV., DEFINITIONS** shall be imputed to **you**.

**D. Breach of Contract**

any claim or suit based on or arising directly or indirectly out of the following:

1. breach of express or implied contract;
2. breach of express or implied warranty;
3. fraud or misrepresentation regarding the formation, terms or performance of a contract; or
4. libel, slander or defamation arising out of or within the contractual relationship;

nor do we have any duty to defend any claim or suit arising from 1. through 4. of the above.

**E. Claims by Associated Entities**

based on or arising out of any claim(s) made against **you** by any person, entity or organization which:

1. is owned, managed, or controlled by **you** or in which **you** have an ownership interest in excess of 25%;
2. in which **you** are an officer, partner, or director; or
3. owns, operates, or manages **you**.

**F. Criminal, Dishonest, Fraudulent, Malicious Conduct or Acts of Intentional Wrongdoing**

based on or arising out of criminal, dishonest, fraudulent or malicious conduct or acts of intentional wrongdoing by the **Insured**; provided, however, that the Company shall provide the **Insured** with a defense of such claim unless or until the dishonest, fraudulent, malicious or act of intentional wrongdoing has been determined by a trial verdict, court ruling, regulatory ruling or legal admission, but such a defense will only be provided in a civil action or regulatory proceeding for claims asserted by a **bodily injury** or **property damage** claimant in his or her individual capacity. The defense of a claim will not waive the rights of the Company to deny indemnity under the applicable Policy.

For purposes of determining the applicability of this exclusion:

1. the facts pertaining to and knowledge possessed by any natural person **Insured** shall not be imputed to any other natural person **Insured**; and
2. only facts pertaining to and knowledge possessed by any **Insured** as set forth in paragraph A. of the definition of **Insured** in Section **IV., DEFINITIONS** shall be imputed to **you**.

**G. Employer's Liability**

based on or arising out of any actual or alleged **bodily injury** to:

1. **your employee** arising out of and in the course of:
  - a. employment by **you**; or
  - b. performing duties related to the conduct of **your business**; or
2. the spouse, **domestic partner**, child, parent, brother or sister of that **employee** as a consequence of 1. a. or b. above.

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This exclusion applies:

- i. whether **you** may be liable as an employer or in any other capacity; and
- ii. to any obligation to share **damages** with or repay someone else who must pay **damages** because of the injury.

Voluntary participation as a human test subject in a clinical trial will not be deemed to be within the course of employment or performance of duties as described in paragraphs 1. a. and b. above.

**H. Expected or Intended Injury**

based on or arising out of any actual or alleged **bodily injury** or **property damage** expected or intended from the standpoint of the **Insured**. This exclusion does not apply to:

1. **bodily injury** resulting from the use of reasonable force to protect persons or property; or
2. **bodily injury** that is intended or can be expected to result from reasonable use of **your product**.

**I. Failure to Prevent Unauthorized Access**

based on or arising out of any actual or alleged failure to prevent unauthorized access to, or unauthorized use of, **your client's**, or **your client's customers'**:

1. confidential or proprietary information; or
2. information systems.

This exclusion applies, but is not limited, to any allegations of loss filed by third-parties based on or arising out any actual or alleged failure in 1. or 2. above.

**J. Fungi or Bacteria**

based on or arising out of:

1. **bodily injury** or **property damage** which would not have occurred, in whole or in part, but for the actual, alleged or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of, any **fungi** or **bacteria** on or within a building or structure, including its contents, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such injury or damage; or
2. any loss, cost or expenses arising out of the abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing, remediating or disposing of, or in any way responding to, or assessing the effects of, **fungi** or **bacteria**, by any **insured** or by any other person or entity.

This exclusion does not apply to any **fungi** or **bacteria** that are on, or are contained in, a good or product intended for bodily consumption.

**K. Intellectual Property Rights**

based on or arising out of a **claim** or **circumstance** of any actual or alleged assertion, infringement or violation, by any person or entity including the **Insured**, of any intellectual property rights, including but not limited to the following:

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1. a copyright, patent, trademark, intellectual design right, collective trade mark, certification mark or service mark or any similar such protections or rights (whether or not any of the foregoing are registered);
2. a trade secret or other type of formula, practice, process, design, instrument, pattern or compilation of information regarded by a business as confidential or proprietary;
3. trade dress or any right protecting any interest in a name, symbol, slogan, style of doing business, or any similar such expression, likeness or idea; or
4. the use of another's name or product in **your** e-mail address, domain name or metatag, or any other similar tactics to mislead another's potential customers.

In the event a **claim** is made against the **Insured** alleging a violation of intellectual property rights, as described above, along with any other allegation, then this exclusion shall apply to preclude coverage for the entire **claim**, even if in the absence of the allegations concerning intellectual property rights any portion of the **claim** would have been covered or a duty to defend the **Insured** would have been owed by us.

**L. Lead**

based on or arising out of:

1. the actual, alleged or threatened exposure at any time to **lead** or **lead-containing** products, or
2. any actual or alleged loss, cost or expense that may be awarded or incurred:
  - a. by reason of a **claim** for any such injury or damage; or
  - b. in complying with a governmental direction or request to test for, monitor, clean up, remove, contain or dispose of **lead**.

This exclusion does not apply to any **biological products**, **pharmaceutical products**, or **medical devices** intended to treat patients with, or protect patients from, **lead poisoning**.

**M. Medical Services**

based on or arising out of **medical services**. However this exclusion does not apply to:

1. physicians, dentists, nurses, emergency medical technicians or paramedics employed by **you** to the extent that they are rendering first aid; or
2. to any **products-completed operations hazard claim** made against a **clinical trial investigator**.

**N. Misuse of Confidential Information**

based on or arising out of any actual or alleged use or misuse of confidential or proprietary information.

**O. Nuclear**

1. under any **Liability Coverage**, to **bodily injury or property damage**:
  - a. with respect to which an **Insured** under this **Policy** is also insured under a nuclear energy liability **Policy** issued by Nuclear Energy Liability Insurance Association, Mutual Atomic Energy Liability Underwriters, Nuclear Insurance Association of Canada or any of their successors, or would be an insured under any such **Policy** but for its termination upon exhaustion of its limit of liability; or
  - b. resulting from the **hazardous properties of nuclear material** and with respect to which (a) any person or organization is required to maintain financial protection pursuant to the Atomic Energy Act of 1954, or any law amendatory thereof, or (b) an **Insured** is, or had this **Policy** not been issued would be, entitled to indemnity from the United States of America, or any agency thereof, under

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any agreement entered into by the United States of America, or any agency thereof, with any person or organization.

2. under any Medical Payments coverage, to expenses incurred with respect to **bodily injury** resulting from the **hazardous properties** of nuclear material and arising out of the operation of a **nuclear facility** by any person or organization.
3. under any Liability Coverage, to **bodily injury** or **property damage** resulting from **hazardous properties** of nuclear material, if:
  - a. the nuclear material (a) is at any **nuclear facility** owned by, or operated by or on behalf of, an **Insured** or (b) has been discharged or dispersed there from;
  - b. the nuclear material is contained in **spent fuel** or **nuclear waste** at any time possessed, handled, used, processed, stored, transported or disposed of, by or on behalf of an **Insured**; or
  - c. the **bodily injury** or **property damage** arises out of the furnishing by an **Insured** of services, materials, parts or equipment in connection with the planning, construction, maintenance, operation or use of any **nuclear facility**, but if such facility is located within the United States of America, its territories or possessions or Canada, this exclusion c. applies only to **property damage** to such nuclear facility and any property thereat.

**P. Pollutants**

based on or arising out of:

1. **bodily injury** or **property damage** which would not have occurred in whole or part but for the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of **pollutants** at any time; or
2. any loss, cost or expense arising out of any:
  - A. request, demand, order or statutory or regulatory requirement that any **Insured** or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of **pollutants**; or
  - B. claim or suit by or on behalf of a governmental authority for **damages** because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of, **pollutants**.

**Q. Property Damage to Impaired Property**

based on or arising out of any actual or alleged **property damage** to **impaired property** or property that has not been physically injured, arising out of:

1. a defect, deficiency, inadequacy or dangerous condition in **your product** or **your work**; or
2. a delay or failure by **you** or someone acting on **your** behalf to perform a contract or agreement in accordance with its terms.

This exclusion does not apply to the loss of use of other property arising out of sudden and accidental physical injury to **your product** or **your work** after it has been put to its intended use.

**R. Property Damage to Property You Own, or in Your Care, Custody or Control**

based on or arising out of any actual or alleged **property damage** to:

1. property **you** own, rent, or occupy, including any costs or expenses incurred by **you**, or any other person, organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property;

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2. premises **you** sell, give away or abandon, if the **property damage** arises out of any part of those premises;
3. property loaned to **you**;
4. personal property in the care, custody or control of any **Insured**; or
5. that particular part of real property on which **you** or any contractors or subcontractors working directly or indirectly on **your** behalf are performing operations, if the **property damage** arises out of those operations.

**S. Property Damage to Your Products**

based on or arising out of any actual or alleged **property damage** to **your products** arising out of such products or any part of such products.

**T. Property Damage to Your Work**

based on or arising out of any actual or alleged **property damage** to **your work** arising out of it or any part of it. This exclusion does not apply if the damaged work or the work out of which the damage arises was performed on **your** behalf by a subcontractor.

**U. Recall of Products, Work or Impaired Property**

based on or arising out of any loss, cost or expense incurred by **you** or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

1. **your product**;
2. **your work**; or
3. **impaired property**;

if such product, work, or property is withdrawn or recalled from the market or from use by any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition in it.

**V. Sexual Abuse**

based on or arising out of the actual, alleged, attempted, proposed or threatened:

1. sexual abuse,
2. molestation,
3. assault, or
4. battery

of any person by an **Insured**.

This exclusion applies regardless of the legal theory or basis upon which an **Insured** is alleged to be liable for any **damages** or injury arising out of the activity described above, including but not limited to assertions of improper or negligent employment, continued employment, investigation, failure to investigate, supervision or failure to supervise.

**W. Silica**

based on or arising out of:

1. the actual, alleged or threatened exposure at any time to silica or silica-containing products, or

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2. any actual or alleged loss, cost or expense that may be awarded or incurred:
  - a. by reason of a claim for any such injury or damage; or
  - b. in complying with a governmental direction or request to test for, monitor, clean up, remove, contain or dispose of silica.

**X. War or Civil Insurrection**

based on or arising out of any actual or alleged war, whether or not declared, or any act or condition incident to war. War includes civil war, insurrection, rebellion or revolution.

**IV. DEFINITIONS**

The following defined words shall have the same meaning throughout this Policy, whether expressed in the singular or the plural and wherever appearing in bold print in this Policy:

**Advisory memorandum**

means a written communication issued by **you** or on **your** behalf to healthcare professionals, customers, product users, suppliers, vendors or the public at large informing them of an actual or alleged defect or deficiency in **your** product or in its labeling.

**Application**

means all signed **applications** for this Policy and for any Policy in an uninterrupted series of Policies issued by the Company, or any of its affiliates, of which this Policy is a renewal or replacement, and any materials submitted or required to be submitted therewith.

**Asbestos**

means the mineral in any form whether or not the asbestos was at any time airborne as a fiber, particle or dust, contained in or formed a part of a product, structure or other real or personal property, carried on clothing, inhaled or ingested, or transmitted by any other means.

**Automobile**

means a land motor vehicle, trailer or semi-trailer designed for travel on public roads, including any attached machinery or equipment. But **automobile** does not include **mobile equipment**.

**Biological product**

means any virus, therapeutic serum, toxin, antitoxin, or analogous product that is:

- A. recognized in the official National Formulary, the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia, Compendium of Pharmaceuticals & Specialties, any provincial formulary, and any supplement to any of these or the equivalent of such documents in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure or any function of the human body; or
- C. a component of any product described in paragraph A. or B. above.

However, **biological product** does not include any pharmaceutical drug, **medical device** or food.

**Bodily injury**

means physical harm, sickness or disease sustained by a person including resulting mental injury, mental anguish, shock or death. It also includes physical harm, sickness, disease, mental injury, mental anguish, shock or death sustained by a spouse, **domestic partner** or any relative of that person as a result of that person's injury.

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**Boxed warning**

means any notice required by the Food and Drug Administration pursuant to 21 CFR 201. 57(a) (4) and (c) (1), by any update to the aforesaid sections of the Code of Federal Regulations, or by any foreign equivalent of such.

**Circumstance**

means an event, act, error or omission reported during the **policy period** from which you reasonably expect that a claim could be made.

**Claim**

means:

- A. a written demand upon an **Insured** for money or services; or
- B. a civil proceeding in a court of law or equity, or arbitration, for money or services, or any appeal therefrom,

against an **Insured**. A claim does not include a **circumstance**.

**Claim expenses**

mean:

- A. fees charged by attorneys designated by the Company or by an **Insured** with the Company's prior written consent;
- B. all other reasonable and necessary fees, costs and expenses resulting from:
  - 1. the investigation of a **circumstance**, or
  - 2. the investigation, adjustment, defense and appeal of a covered **claim**if incurred by the Company, or by an **Insured** with the Company's prior written consent, including, but not limited to, premiums for any appeal bond, attachment bond or similar bond but without any obligation of the Company to apply for or furnish any such bond;
- C. prejudgment interest awarded against you on that part of a judgment the Company pays. If the Company makes an offer to pay the applicable limit of liability, the Company will not pay any prejudgment interest based on that period of time after such offer; or
- D. interest on the full amount of a judgment that accrues after entry of the judgment and before the Company has paid, offered to pay or deposited in court the part of the judgment that is within the applicable limit of liability.

However, claim expenses do not include:

- 1. salaries, loss of earnings or other remuneration by or to any **Insured**; or
- 2. fees and expenses of independent adjusters engaged by the Company or salaries of the Company's officials or Company's **employees**, other than fees and expenses charged by the Company's employed attorneys who may be designated to represent the **Insured** with the **Insured's** consent.

**Class 1 product recall**

means that you or the United States Food and Drug Administration, or any foreign equivalent, have determined your **product** poses a situation in which there is a reasonable probability that the use of or exposure to your **product** will cause serious adverse health consequences or death.

**Clinical trial**

means an organized study, test or written protocol that uses human subjects to establish the effectiveness, bioequivalence or safety of your **products**.

**Clinical trial consultant**

means any medical intern, resident, technician, nurse, physician or other medical professional, who provides advice to a **clinical trial investigator**.

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**Clinical trial consultant services**

mean professional advice or demonstration by a clinical trial consultant of procedures to be performed by a clinical trial investigator in connection with a clinical trial as outlined in the written protocol of such clinical trial.

**Clinical trial investigator**

means the individuals who provide services in the clinical trial testing of your products as outlined in the written protocol of such clinical trial. Clinical trial investigators do not include human test subjects in the clinical trial.

**Clinical research organization**

means any entity that provides services in connection with organizing, administering or running clinical trials.

**Coverage relationship**

means that period of time between the effective date of the first Policy issued by the Company to the First Named Insured and the cancellation or expiration date of that Policy or, if renewed, the last renewal Policy in a consecutive series of renewals issued by the Company to the First Named Insured, where there has been no gap in coverage.

**Damages**

mean judgments; awards; and settlements, but only if made with the Company's prior written consent. Damages do not include:

- A. restitution and disgorgement of profits, fees, costs and expenses paid or incurred or charged by an Insured, no matter whether claimed as restitution of specific funds, forfeiture, financial loss, set-off or otherwise; nor economic injuries that are a consequence of any of the foregoing;
- B. civil or criminal fines, sanctions, penalties or forfeitures, whether pursuant to law, statute, regulation or court rule;
- C. the multiplied portion of multiplied awards imposed pursuant to any statute or regulation requiring such awards;
- D. injunctive or declaratory relief;
- E. any amount that is not insurable under any applicable statute or regulation;
- F. any amounts for which an Insured is liable due to an act or omission in knowing violation of any written contract or agreement; or
- G. plaintiff's attorney fees associated with any of the above.

Notwithstanding anything to the contrary above, and subject to this Policy's other terms, conditions and limitations, damages shall include punitive and exemplary damages. Enforceability of this paragraph shall be governed by such applicable law that most favors coverage for such punitive or exemplary damages.

**Domestic partner**

means any person qualifying as such under any federal, state or local laws or under your employee benefit plans.

**Employee**

means any person whose work or service is directed and controlled by you. It includes a leased worker, a volunteer and a temporary worker.

**Executive officer**

means:

- A. a person holding any of the officer positions created by your charter, constitution, by-laws or any other similar governing document;
- B. your corporate risk manager; or
- C. any employee who is responsible for your insurance or claim reporting.

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**First Named Insured**

means the first entity listed in the Declarations.

**Fungi**

means any type or form of fungus, including mold or mildew and any mycotoxins, spores, scents or byproducts produced or released by fungi.

**Hazardous properties**

means including radioactive, toxic or explosive properties.

**Impaired property**

means tangible property, other than **your product** or **your work**, that cannot be used or is less useful because:

- A. it incorporates **your product** or **your work** that is known or thought to be defective, deficient, inadequate or dangerous; or
- B. **you** have failed to fulfill the terms of a contract or agreement;

if such property can be restored to use by:

- A. the repair, replacement, adjustment or removal of **your product** or **your work**; or
- B. **your** fulfilling of the terms of the contract or agreement.

**Institutional review board**

means a board, committee (including an ethics committee), panel or similar group designated, directed or requested by a person or organization to review or approve clinical trials.

**Insured**

means **you** and any of the following but solely with respect to liability arising out of **your work** or **your product**:

- A. any individual who was, is or becomes **your** officer, director, member or manager (of a limited liability company), or partner but solely with respect to the conduct of **your** business;
  - B. **your** stockholders, but only with respect to their liability as stockholders;
  - C. **your employees**, with respect to **products-completed operations hazard claims**, solely for acts within the scope of their employment by **you** or while performing duties related to the conduct of **your** business; however, none of these **employees** is an **Insured** for:
    - 1. **bodily injury**:
      - a. to **you**, to **your** directors, officers, members or managers, partners, or to a co-employee while such injured person is either in the course of his or her employment or performing duties related to the conduct of **your** business, but voluntary participation as a human test subject in a clinical trial will not be deemed to be within the scope of employment or performance of duties described herein;
      - b. to the spouse, **domestic partner**, child, parent, brother or sister of such injured person as a consequence of paragraph a. above; or
      - c. for which there is any obligation to share **damages** with or repay someone else who must pay **damages** because of the injury described in paragraphs a. or b. above;
    - 2. **property damage to property**:
      - a. owned, occupied or used; or
      - b. rented to, in the care, custody or control of, or over which physical control is being exercised for any purpose;
- by **you**, any of **your employees**, any partner or member (if **you** are a partnership or joint venture), or any member (if **you** are a limited liability company);

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- D. any person (other than **you** or **your employee**), or any organization while acting as **your** real estate manager;
  - E. clinical research organizations, medical or biotechnology advisors, clinical trial consultants, institutional review boards and clinical trial investigators (other than **you** or **your employees**); however, no such person or entity is an **Insured** with respect to:
    - 1. any representation or warranty not authorized by **you**; or
    - 2. any physical or chemical change in **your product** made intentionally by such person without **your** consent;
  - F. medical sales consultants; however, no such person or entity is an **Insured** with respect to:
    - 1. any representation or warranty not authorized by **you**;
    - 2. any physical or chemical change in **your product** made intentionally by such person without **your** consent; or
    - 3. such person or entity's rendering or failing to render advice, unless the injury or damage arises directly out of the use of **your products**;
  - G. persons or entities who are vendors of **your products**, but they are **Insureds** only with respect to their liability for damages resulting from the distribution or sale of **your products** in the regular course of their business; however, no such person or entity is an **Insured** with respect to:
    - 1. any representation or warranty not authorized by **you**;
    - 2. any physical or chemical change in **your product** made intentionally by the vendor;
    - 3. repackaging, unless unpacked solely for the purpose of inspection, demonstration, or testing, or the substitution of parts under instruction from the manufacturer and then repacked in the original container;
    - 4. failure to make such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business in connection with the distribution or sale of **your products**; or
    - 5. demonstration, installation, servicing or repair operations, except such operations performed at the vendor's premises in connection with the sale of **your products**;
- further no person or entity from whom **you** have acquired **your products**, or any container, ingredient or part entering into, accompanying or containing **your products**, is an **Insured** under this provision;
- H. any person or entity to whom or to which **you** are obligated by virtue of a written contract, agreement or permit to provide such insurance as afforded by this Policy, but only with respect to liability arising out of **your product** or **your work** performed by **you** or on **your** behalf for that **Insured**; however, this provision does not apply:
    - 1. unless the written contract or agreement has been executed, or the permit has been issued, prior to the **bodily injury, property damage, or personal or advertising injury** to a clinical trial participant. The contract or agreement will be considered executed when an **Insured's** performance begins, or when it is signed, whichever happens first; or
    - 2. to any person or entity:
      - a. for:
        - i. **bodily injury,**
        - ii. **property damage, or**
        - iii. **personal or advertising injury to a clinical trial participant,**
 arising out of its sole negligence; or
      - b. included as an **Insured** by an endorsement issued by the Company and made a part of this Policy.

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For sub-sections E., F., G. and H., such persons or entities are Insureds only to the extent contained in a written contract or agreement and only up to the amount required by such written contract or agreement, but notwithstanding anything contained in a written contract or agreement, the Company shall not be liable for greater coverage or limits of insurance than provided for in this Policy.

For subsections A.-H., all claims for damages because of bodily injury to the same person, including damages alleged by any person or organization for care, loss of services, or death resulting at any time from the bodily injury, will be deemed to have been made at the time the first of those claims is made against any Insured.

For subsections A.-H., all claims for damages because of property damage or personal or advertising injury alleged by the same person or organization will be deemed to have been made at the time the first of those claims is made against any Insured

**Insured contract**

means that part of any written contract or agreement pertaining to your operations or facilities under which you assume the tort liability of another to pay damages because of bodily injury or property damage to a third person or organization, or personal or advertising injury to a clinical trial participant, provided such contract or agreement is made prior to the bodily injury, property damage, or personal or advertising injury to a clinical trial participant. Tort liability means a liability that would be imposed by law in the absence of any contract or agreement.

**Lead**

means the element in any form.

**Loading or unloading**

means the handling of property:

- A. after it is moved from the place where it is accepted for movement into or onto an aircraft, watercraft or automobile;
- B. while it is in or on an aircraft, watercraft or automobile; or
- C. while it is being moved from an aircraft, watercraft or automobile to the place where it is finally delivered,

but loading or unloading does not include the movement of property by means of a mechanical device, other than a hand truck, that is not attached to the aircraft, watercraft or automobile.

**Local admitted policy**

means any Policy required to be issued by a duly authorized insurer in a jurisdiction outside of the United States, Puerto Rico or Canada that provides compulsory coverage in such jurisdiction.

**Management control**

means:

- A. owning interests representing more than 50% of the voting, appointment or designation power for the selection of:
  - 1. a majority of:
    - a. the Board of Directors of a corporation;
    - b. the management committee of a joint venture; or
    - c. the members of the management board of a limited liability company; or
  - 2. the general partners of a limited partnership, or one or more managing partners of a partnership other than a limited partnership; or

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- B. having the right, pursuant to the **First Named Insured's** by-laws, charter, operating agreement, partnership agreement or similar documents, to elect, appoint or designate:
  - 1. a majority of:
    - a. the Board of Directors of a corporation;
    - b. the management committee of a joint venture; or
    - c. the members of the management board of a limited liability company; or
  - 2. the general partners of a limited partnership, or one or more managing partners of a partnership other than a limited partnership.

**Medical device**

means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, component part or accessory that is:

- A. subject to United States Food and Drug Administration regulation, Health Canada regulation or the equivalent of such regulations in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans; or
- C. intended to affect the structure or any function of the human body;

and does not achieve its primary intended purposes through chemical or biological action within or upon the human body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

However, **medical device** does not include any **pharmaceutical drug, biological product** or food.

**Medical or biotechnology advisors**

means an entity or individuals, other than **you** or **your employees**, who are serving, or have served as **your** advisor or consultant in a review of the design or development of **your products**.

**Medical expenses**

means reasonable expenses for necessary:

- A. first aid administered at the time of an accident;
- B. medical, surgical, x-ray and dental services, including prosthetic devices; or
- C. ambulance, hospital, professional nursing and funeral services.

**Medical sales consultant**

means an entity or individuals, other than **you** or **your employees**, providing advice or demonstrating procedures in connection with the sale or distribution of **your products** on the condition that such consultant does not render any direct patient care or medical services in connection with the sale or distribution of **your products**.

**Medical services**

means

- A. dental, medical, mental health, nursing, surgical, imaging, clinical testing or other similar service providing direct care to a patient and performed by a medical intern, resident, technician, nurse, physician or other medical professional;
- B. the furnishing of food, beverages, medications or appliances in connection with such services; or
- C. the postmortem handling of human bodies.

**Mobile equipment**

means any of the following types of land vehicles, including any attached machinery or equipment:

- A. bulldozers, farm machinery, forklifts and other vehicles designed for use principally off public roads;
- B. vehicles maintained for use solely on or next to premises **you** own or rent;

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- C. vehicles that travel on crawler treads;
- D. vehicles, whether self-propelled or not, maintained primarily to provide mobility to permanently mounted:
  - 1. power cranes, shovels, loaders, diggers or drills; or
  - 2. road construction or resurfacing equipment such as graders, scrapers or rollers;
- E. vehicles not described in A., B., C. or D. above that are not self-propelled and are maintained primarily to provide mobility to permanently attached equipment of the following types:
  - 1. air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment; or
  - 2. cherry pickers and similar devices used to raise or lower workers;
- F. vehicles not described in A., B., C. or D. above maintained primarily for purposes other than the transportation of persons or cargo.

However, self-propelled vehicles with the following types of permanently attached equipment are not mobile equipment but will be considered automobiles:

- 1. equipment designed primarily for:
  - a. snow removal;
  - b. road maintenance, but not construction or resurfacing; or
  - c. street cleaning;
- 2. cherry pickers and similar devices mounted on automobile or truck chassis and used to raise or lower workers; and
- 3. air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment.

**Named Insured**

means any entity listed as such in the Declarations or as amended by endorsement to this Policy.

**Newly acquired subsidiary**

means any entity, newly formed or acquired by the First Named Insured or any subsidiary during the policy period but only for 90 days after such formation or acquisition. In order for coverage to continue beyond such 90 day period, the Company must have specifically agreed in writing to add such entity as a subsidiary to the Policy by endorsement specifying the terms and conditions of its coverage.

**Nuclear facility**

means:

- A. any nuclear reactor;
- B. any equipment or device designed or used for (a) separating the isotopes of uranium or plutonium, (b) processing or utilizing spent fuel, or (c) handling, processing or packaging nuclear waste;
- C. any equipment or device used for the processing, fabricating or alloying of special nuclear material if at any time the total amount of such material in the custody of an Insured at the premises where such equipment or device is located consists of or contains more than 25 grams of plutonium or uranium 233 or any combination thereof, or more than 250 grams of uranium 235;
- D. any structure, basin, excavation, premises or place prepared or used for the storage or disposal of nuclear waste; and

includes the site on which any of the foregoing is located, all operations conducted on such site and all premises used for such operations.

**Nuclear material**

means source material, special nuclear material or by-product material.

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**Nuclear reactor**

means any apparatus designed or used to sustain nuclear fission in a self supporting chain reaction or to contain a critical mass of fissionable material. **Property damage** includes all forms of radioactive contamination of property.

**Nuclear waste**

means any waste material (a) containing **by-product material** other than the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its **source material** content, and (b) resulting from the operation by any person or organization of any **nuclear facility** included under the first two paragraphs of the definition of nuclear facility.

**Occurrence**

means an accident, including continuous or repeated exposure to the same general harmful conditions.

**Personal or advertising injury**

means injury, including emotional distress and mental anguish, arising out of:

- A. defamation or other tort related to disparagement or harm to the character, reputation or feelings of any person or organization, including libel, slander, product disparagement, trade libel, negligent or intentional infliction of emotional distress, outrage or outrageous conduct;
- B. false arrest, wrongful detention, false imprisonment, wrongful entry or eviction or other invasion of the right of private occupancy, malicious prosecution or violation of an individual's or entity's right of privacy;
- C. invasion, infringement or interference with rights of privacy or publicity, including false light, public disclosure of private facts, intrusion and commercial appropriation of name or likeness;
- D. infringement of copyright, title, slogan, trademark, trade name, trade dress, trade secrets, logo, service mark or service name;
- E. the use of another's advertising idea; or
- F. plagiarism, piracy, misappropriation of ideas under implied contract or other misappropriation of property rights, ideas or information.

**Pharmaceutical drug**

means a synthetic or natural chemical:

- A. recognized in the official National Formulary, the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia, Compendium of Pharmaceuticals & Specialties, any provincial formulary or any supplement to any of these or the equivalent of such documents in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure of any function of the human body; or
- C. as a component of any product described in paragraph A. or B. above.

However, **pharmaceutical drug** does not include any **biological product**, **medical device** or food.

**Policy period**

means the period of time shown in the Declarations of this Policy or as amended by endorsement or cancellation.

**Pollutants**

means any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled, reconditioned or reclaimed.

**Products-completed operations hazard**

means:

- A. **bodily injury or property damage** arising out of **your product or your work**; or

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- B. **personal or advertising injury** but solely to the extent such **personal or advertising injury** arises out of **clinical trials** sponsored by you and solely to the extent a **clinical trial** participant incurs such **personal or advertising injury**.

However, **products-completed operations hazard** does not include **bodily injury** or **property damage** arising out of:

1. the transportation of property, unless the **bodily injury** or **property damage** arises out of a condition in or on a vehicle created by the **loading or unloading** of it; or
2. the existence of tools, uninstalled equipment, or abandoned or unused materials.

**Products-completed operations hazard claim**

means a claim alleging a **products-completed operations hazard** and arising out of an **occurrence**.

**Property damage**

means:

- A. **physical injury** to tangible property, including the loss of use thereof. All such loss of use shall be deemed to occur at the time of the physical injury that caused it; or
- B. loss of use of tangible property that has not been physically injured or destroyed. All such loss of use shall be deemed to occur at the time of the **occurrence** that caused it.

**Related claims**

means all **claims** arising out of a single **occurrence** or **related occurrences**.

**Related occurrence**

means an **occurrence** giving rise to **bodily injury**, **property damage** or **personal or advertising injury** to two or more persons or properties which **bodily injuries**, **property damage** or **personal or advertising injuries** are attributable directly, indirectly or allegedly to the same actual, or alleged event, condition, cause, defect, hazard, advice or decision in the design, formulation, manufacturing, distribution, sale, testing, use, operation, maintenance, repair or replacement of **your product** or **your work**. Such **related occurrence** exists regardless of:

- A. when or where such **bodily injuries**, **property damage** and or **personal or advertising injuries** occur; or
- B. the number of such **bodily injuries**, **property damage** and or **personal or advertising injuries**.

**Silica**

means silicon dioxide occurring in crystalline, amorphous or impure forms, silica particles, silica dust or silica compounds. It does not include processed colloidal silicon dioxide.

**Source material, special nuclear material, and by-product material**

mean the meanings given them in the Atomic Energy Act of 1954 or in any law amendatory thereof.

**Spent fuel**

means any fuel element or fuel component, solid or liquid, which has been used or exposed to radiation in a **nuclear reactor**.

**Submission materials**

means any materials provided by you or on your or any other insured's behalf in connection with the application process for this insurance.

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**Subsidiary**

means any entity in which the **First Named Insured**, directly or indirectly, had **management control** on the inception date of this Policy. On the date during the **policy period** that the **First Named Insured** ceases to have such **management control** of such entity, such entity shall cease to be a **subsidiary** under the terms of this Policy. In such event, coverage will be provided to such **subsidiary** under the Policy but only with respect to **occurrences** that happen prior to such date in accordance with all other terms and conditions of this Policy. No coverage will be afforded under the Policy with respect to **claims** made against such **subsidiary** based on any **occurrences** that happened on or subsequent to such date.

**Takeover**

means:

- A. the acquisition by another entity or person, or group of entities or persons acting in concert, of:
  - 1. the ownership or control of voting stock of the **First Named Insured** resulting in such entity, person or group owning or controlling more than 50% of the voting stock of the **First Named Insured**; or
  - 2. assets of the **First Named Insured** resulting in such entity, person or group owning more than 50% of the total consolidated assets of the **First Named Insured** as of the date of the **First Named Insured's** most recent audited consolidated financial statement prior to such acquisition;
- B. the merger of the **First Named Insured** into another entity such that the **First Named Insured** is not the surviving entity; or
- C. the consolidation of the **First Named Insured** with another entity.

**You (or Your)**

means any **Named Insured** and any **subsidiary** or any newly acquired **subsidiary**.

**Your product**

means:

- A. any goods or products including, but not limited to, **biological products**, **pharmaceutical drugs** or **medical devices** manufactured, developed, designed, created, tested, sold, leased, licensed, rented, handled, marketed, distributed to others or disposed of, by **you** or others on **your** behalf; and
- B. containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products.

**Your product** includes:

- 1. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation or safety of **your product**; and
- 2. the providing of or failure to provide training, warnings or instructions.

**Your work**

means:

- A. work or operations performed by **you** or on **your** behalf, in compliance with all applicable laws, statutes or ordinances; and
- B. materials, parts or equipment furnished in connection with such work, operations or services.

**Your work** includes:

- 1. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation, safety or maintenance of **your work**; and
- 2. the providing of, or failure to provide, training, warnings or instructions.

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**V. CONDITIONS****A. Your Duties if there is a Claim**

It is a condition precedent to coverage that an Insured:

1. notify the Company as soon as reasonably possible of any claim;
  - a. such notice must be in writing and be sent to the attention of Navigators Specialty Claims:
    - i. by email to: RBCClaims@navg.com;
    - ii. by fax to: (847) 285-9003; or
    - iii. by mail to: 1375 E. Woodfield Rd., Suite 720, Schaumburg, IL 60173
  - b. such notice must be given to the Company no later than ninety days (90) after termination or expiration of the coverage relationship, or during the Extended Reporting Period, if applicable;
2. specify the names and addresses of the persons making a claim against an Insured and provide the Company with information on the time, place and nature of the claim;
3. promptly forward to the Company all documents that the Insured receives in connection with the claim;
4. fully cooperate with the Company or its designee in the defense of a claim, including but not limited to assisting the Company in the conduct of suits or other proceedings, settlement negotiations, and the enforcement of any right of contribution or indemnity against another who may be liable to an Insured;
5. shall attend hearings and trials and assist in securing evidence and obtaining the attendance of witnesses; and
6. will not voluntarily make any payment, admit liability, assume any obligation or incur any expense, other than first aid, without the Company's prior written approval.

After an Insured reports a claim and the Insured has the right under any contract to either reject or demand arbitration or other alternative dispute resolution process, the Insured shall only do so with the Company's prior written consent.

**B. Your Rights in the Event of a Circumstance**

If, during the policy period, you report a circumstance for which there may be coverage under this Policy, and you give the Company written notice containing:

1. what happened, and the details of your work, your product or activities you performed that might give rise to a claim;
2. the nature of any possible injury or damages;
3. how you first became aware of such circumstance;
4. the identity of the specific Insureds allegedly responsible for such specific activities; and
5. the nature of the potential demand for money or services that may be sought in consequence of such specific activities,

then any claim otherwise covered that may subsequently be made against an Insured during the Coverage Relationship, during the automatic Extended Reporting Period, or any Supplemental Extended Reporting Period if purchased, arising out of such circumstance shall be deemed to have been made against such Insured on the date the Company received written notice of the circumstance.

**C. Mandatory Notice of Advisory Memorandum, Class 1 Product Recall or Boxed Warning**

You must see to it that the Company is advised as soon as reasonably possible of any advisory memorandums or class 1 product recalls issued during this policy period. You must also see to it that the Company is advised as soon as reasonably possible of boxed warnings added to, or revised for, any of your previously approved product labeling during this policy period. Timely reporting of such events is required for coverage to be afforded for any future losses or claims that may arise as a result of these events.

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**D. When a Claim shall be Deemed Made**

A claim is deemed made:

1. in the case of a written demand, on the **executive officer's** receipt of such demand; or
2. in the case of a civil action proceeding in a court of law or equity or arbitration, or a regulatory proceeding, on the date of service upon, or other receipt by, **you** of a complaint against **you** in such proceeding or arbitration.

**E. Transfer of Rights of Recovery Against Others**

If an **Insured** has rights to recover all or part of any payment we have made under this Policy, those rights are transferred to us. The **Insured** must do nothing after loss to impair them. At the Company's request, the **Insured** will bring suit or transfer those rights to the Company and help it enforce them.

However, the Company will waive any right of recovery it may have against any person or entity because of payments it made for injury or damage arising out of **your work** or **your products** under a written contract or agreement with that person or entity. This waiver applies only to persons or entities with whom **you** have a written contract or agreement, executed prior to the **occurrence**, that requires **you** to waive **your** rights of recovery.

The amount recovered shall be apportioned in the inverse order of payment of **damages** to the extent of actual payment. **Claim expenses** shall be apportioned in the ratio of respective recoveries.

**F. Premium**

All premium charges under this Policy will be computed according to the rules, rates and rating plans that apply at the effective date of the current **policy period**.

**You** shall maintain records of such information as it is necessary for auditable premium computation and shall send copies of such records to the Company at the end of the **policy period** and at such times during the **policy period** as the Company may direct. Subsequent to audit by the Company, **you** shall forward to the Company any additional premiums warranted by such audit.

**G. Bankruptcy**

In the event of **your** bankruptcy, insolvency, receivership or any refusal or inability of **you** to pay **damages** to which this Policy applies, the insurance afforded by this Policy shall not replace or supplement the deductible or self-insured retention but shall apply in the same manner as though **you** were willing and able to pay. In no event shall the Company assume **your** responsibilities or obligations.

**H. Changes**

Notice to or knowledge possessed by any person shall not create a waiver or a change in any part of this Policy or estop the Company from asserting any right under the terms of this Policy. The policy's terms shall not be waived or changed except by an endorsement issued by and signed by an authorized representative of the Company.

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**I. Assignment**

Assignment of interest under this Policy is prohibited and shall not bind the Company unless and until its consent is endorsed hereon.

**J. Cancellation**

This Policy may be canceled by the **First Named Insured** by surrender thereof to the Company or by mailing to the Company written notice stating when thereafter the cancellation shall be effective. This Policy may be canceled or non-renewed by the Company by mailing to the **First Named Insured** at the address shown in this Policy written notice stating when, not less than 90 days thereafter, such cancellation or non-renewal shall be effective except that for cancellation because of nonpayment of premium which shall be effective not less than 10 days after such notice is mailed to the **First Named Insured**. The mailing of such notice shall be sufficient proof of notice. The time of the surrender or the effective date and hour of cancellation stated in the written notice shall become the end of the **policy period**. Electronic delivery of such written notices either by the **First Named Insured** or by the Company shall be equivalent to mailing.

If the Company cancels this Policy, a refund due shall be computed on a pro-rata basis and shall be promptly returned to the **First Named Insured**; however, if the **First Named Insured** cancels this Policy, the refund due shall be 90% of the pro-rata unearned paid premium, or 75% of the total policy term premium at inception of this Policy, whichever is less, but subject to the minimum premiums shown in the Declarations. The **First Named Insured** may elect in writing to the Company to have any return premium due applied to the additional premium charged for any Supplemental Extended Reporting Period, if purchased.

Premium adjustment may be made either at the time cancellation is effective or as soon as practicable after cancellation becomes effective, but payment or tender of unearned premium is not a condition of cancellation.

**K. Other Insurance**

If the **Insured** is entitled to be indemnified or otherwise covered in whole or in part by any other valid and collectible insurance, self insurance or Indemnity agreement for any **claim** which otherwise would have been indemnified in whole or in part by this Policy, the limits of liability specified in the Declarations shall apply in excess of, and shall not contribute to that **claim**. Solely with respect to any **local admitted policy** the Company shall only be liable for any **damages or claim expenses** that are also covered under the terms and conditions of this Policy to the extent it would have been liable had you purchased and maintained such **local admitted policy**. This paragraph does not apply to any other insurance that was bought specifically to apply in excess of the limits of liability shown in the Declarations of this Policy.

The Company will have no duty under this Policy to defend an **Insured** against any **claim** if any other insurer has a duty to defend the **Insured** against that **claim**. If no other insurer defends, the Company will undertake to do so, but it will be entitled to the **Insured's** rights against all those other insurers.

Solely with respect to any person or organization covered pursuant to section IV. **DEFINITIONS**, the definition of **Insured**, the insurance afforded by this Policy is primary and non-contributory over any other primary insurance available to such **Insured** when required by written contract.

**L. Currency**

The limits, retentions, premiums and losses of this Policy are payable in United States currency unless otherwise specified in the Declarations.

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#### **M. Action Against the Company**

No person or entity has a right under this Policy:

1. to join the Company as a party or otherwise bring it into a suit asking for damages from an Insured; or
2. to sue the Company on this Policy unless all terms have been fully complied with.

#### **N. Inspection and Audit**

The Company shall be permitted but not obligated to inspect **your** property and operations at any time. Neither the Company's right to make inspections nor the making thereof nor any report thereon shall constitute an undertaking, on behalf of or for the benefit of **you** or others, to determine or warrant that such property or operations are safe or healthful, or are in compliance with any law, rule or regulation.

The Company may examine and audit **your** books and records at any time during the **policy period** and extensions thereof and within three years after the final termination of this Policy.

#### **O. Sole Agent**

The **First Named Insured** is authorized to act on behalf of all **Insureds** with respect to giving or receiving notice of cancellation, non-renewal, premium or changes in this Policy or requesting a Supplemental Extended Reporting Period endorsement.

#### **P. Entire Contract**

By acceptance of this Policy **you** agree that:

1. all of the information and statements provided to the Company by **you** are true, accurate and complete and shall be deemed to constitute material representations made by all of the **Insureds**;
2. this Policy is issued in reliance upon **your** representations;
3. this Policy, endorsements thereto, together with the completed and signed **application** (which is deemed to be incorporated herein) embody all of the agreements existing between the **Insureds** and the Company and shall constitute the entire contract between the **Insureds** and the Company; and
4. the willful or intentional misrepresentation of any material matter by **you** or **your agent** will render this Policy null and void and relieve the Company from all liability herein.

#### **Q. Territory**

This insurance applies anywhere in the world regardless of where the **occurrence** takes place or where a **claim** is brought, subject to the following:

1. Solely with respect to any **claim** brought outside of the United States and Canada, this insurance is not a substitute for any **local admitted policy**. The Company assumes no responsibility for the furnishing of certificates, evidence of insurance or bonds in any country in which it is not an admitted or authorized insurer. The Company shall not be liable for any fine or penalty imposed upon an **Insured** or any person or entity covered under this Policy, for failing to obtain insurance from an admitted or duly authorized insurer, nor for any other failure to comply with an insurance law of jurisdiction in which it is not an admitted or authorized insurer.
2. Notwithstanding anything to the contrary in this Policy, with respect to any **claim** brought outside of the United States, Puerto Rico or Canada, the **Insured** and not the Company, shall be obligated to assume charge of and pay the costs of the investigation and defense of any such **claims**. The Company, however, has the right to approve in writing the retention of any defense counsel or to participate with the **Insured** in the choice of arbitrators or mediators. The Company also has the right to be kept fully informed, or to

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have our designated representative kept fully informed, by the Insured concerning the conduct of such defense or such arbitration or mediation.

3. Solely with respect to any claim brought outside the United States, Puerto Rico or Canada, the Company will reimburse the Insured for, or at our sole option, pay on the Insured's behalf, those sums that the Insured becomes legally obligated to pay as damages and claim expenses to which this insurance applies.

Any disputes between an Insured and the Company as to whether there is coverage under this Policy must be filed in the courts of the United States of America, Puerto Rico or Canada.

#### **R. Extended Reporting Periods**

Extended Reporting Periods do not extend the **policy period** or change the scope of coverage provided, nor do they act to reinstate or increase any of the limits of liability. They apply only to claims that occur before the end of the **policy period** but not before the retroactive date shown in the Declarations. Extended Reporting Periods begin at the end of the **coverage relationship** and apply to claims first made and reported to us during the Extended Reporting Periods. A claim first made and reported to us during Extended Reporting Periods will be deemed to have been made on the last day of the **policy period**.

1. **Automatic Extended Reporting Period**  
The Company will provide an automatic, non-cancelable Extended Reporting Period of 90 days at no additional premium if no other insurance is purchased by you to replace this Policy. With respect to any **circumstance** reported to the Company, all claims associated with the reported **circumstance** must be reported within 5 years of the end of the **coverage relationship** in accordance with **Section V., CONDITIONS, paragraph B., Your Rights In The Event of a Circumstance**.
2. **Supplemental Extended Reporting Period (Optional)**  
An optional Supplemental Extended Reporting Period of up to a maximum of 84 months can be purchased to replace the Automatic Extended Reporting Period. To obtain a Supplemental Extended Reporting Period, you must make a request to the Company in writing within 90 days after the end of the **policy period**, or the effective date of cancellation. An additional premium of not more than 200% of the adjusted Annual Premium will be charged for this option.

Purchasing a Supplemental Extended Reporting Period does not change the 5 year limit to report claims associated with any reported **circumstance**.

Once in effect, a Supplemental Extended Reporting Period may not be canceled unless you fail to pay additional premiums or premium audits when due.

#### **S. Separation of Insureds**

Except with respect to the limits of liability, and any rights or duties specifically assigned in this Policy to the **First Named Insured**, this insurance applies:

1. as if each of you were the only you; and
2. separately to each Insured against whom a claim is made.

#### **T. Change of Status of Insureds**

1. **Takeover of the First Named Insured:** In the event of a takeover of the **First Named Insured**, this Policy shall automatically and without any notification terminate effective as of the date of such **takeover**, unless the Company is notified in writing of the **takeover** prior to the **takeover effective date** and agrees in writing to continue this Policy beyond the effective date of **takeover** and the **First Named Insured** accepts any special terms, conditions and exclusions and pays any additional premium charge required by the Company.

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2. **Cessation of Subsidiary:** if any entity ceases to be a subsidiary, such subsidiary shall cease to be an Insured under this Policy and all coverage for such subsidiary under this Policy shall terminate with respect to such subsidiary without any notification on the effective date of such cessation, unless the Company is notified in writing of such cessation prior to the effective date thereof and agrees in writing to continue coverage for such subsidiary, and the First Named Insured accepts any special terms, conditions and exclusions and pays any additional premium charge required by the Company.

#### **U. U.S. Economic and Trade Sanctions Limitations Clause**

No insurer shall be deemed to provide cover and no insurer shall be liable to pay any claim or provide any benefit hereunder to the extent that the provision of such cover, payment of such claim or provision of such benefit would expose that insurer to any sanction, prohibition or restriction under the trade or economic sanctions, laws or regulations of the United States of America.

The United States of America trade or economic sanctions, laws or regulations shall include, but not be limited to, those sanctions administered and enforced by the U.S. Treasury Department's Office of Foreign Assets Control (OFAC).

#### **V. Estates, Legal Representatives and Spouses**

The estates, heirs, legal representatives, assignees, spouses and any domestic partner of natural person Insureds shall be considered Insureds under this Policy; provided, however, coverage is afforded to such estates, heirs, legal representatives, assignees and spouses only for a claim arising solely out of their status as such and, in the case of a spouse or domestic partner, where such claim seeks damages from marital community property, jointly held property or property transferred from the Insured to the spouse or domestic partner.

#### **W. Service of Suit**

In the event the Company fails to pay an amount alleged to be due hereunder, the Company, at the request of the First Named Insured, will not dispute personal jurisdiction in any state within the United States. Nothing herein constitutes or should be understood to constitute a waiver of the Company's rights to commence an action in any court of competent jurisdiction in the United States, to remove an action to United States District Court, to seek a transfer of an action to another court as permitted by law, or to seek the dismissal of an action based upon the doctrine of forum non conveniens.

Service of process in such suit shall be made upon:

Name: Navigators Management Company  
Attn: General Counsel  
Address: 400 Atlantic Street, 8<sup>th</sup> Floor, Stamford, CT 06901

and in any suit instituted against such person upon this Policy, the Company will abide by the final decision of such court or of any appellate court in the event of an appeal.

The General Counsel is authorized and directed to accept service of process on behalf of the Company in any such suit and, upon the request of the First Named Insured, to give a written undertaking to the First Named Insured that he or she will enter a general appearance upon the Company's behalf in the event such suit shall be instituted.

Further, pursuant to any statute of any state, territory or district of the United States that makes provision therefor, the Company hereby designates the Superintendent, Commissioner or Director of Insurance or other officer specified for that purpose in the statute, or his successor or successors in office, as its true and lawful

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attorney upon whom may be served any lawful process in any action, suit or proceeding instituted by or on behalf of any **Named Insured** or any beneficiary hereunder arising out of this contract of insurance, and hereby designates the above-named as the person to whom the said officer is authorized to mail such process or true copy thereof.

**X. Headings**

The descriptions in the headings of this Policy are solely for convenience, and form no part of the terms and conditions of coverage.

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**THIS ENDORSEMENT CHANGES THE POLICY  
PLEASE READ IT CAREFULLY**

**Navigators Life Sciences  
GLS Elite Plus Coverage Endorsement**

This endorsement modifies insurance provided under the following:  
**PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE POLICY**

I) The following is added to Section I. **INSURING AGREEMENTS** of this policy:

**D. Supplementary Benefits**

Subject to paragraph B. **When Coverage Applies** of Section I. **INSURING AGREEMENTS**:

**1. Mitigation Expenses**

- a. The Company will reimburse you for 90% of the mitigation expenses subject to the mitigation expenses sublimit of liability set forth in the Declarations provided that prior to incurring any mitigation expenses:
  - i. you report the claim or circumstance for which you intend to incur such mitigation expenses in accordance with Section V., **CONDITIONS**, paragraphs A. and B.;
  - ii. you provide the Company with details of the action being contemplated by you to minimize any potential damages arising out of such claim or circumstance and the amount of mitigation expenses that are contemplated in connection with such action;
  - iii. the Company provides written approval of any mitigation expenses prior to such mitigation expenses being incurred. No mitigation expenses will be approved by the Company that are requested less than five business days prior to the planned incurrence of such mitigation expenses; and
  - iv. you cooperate with the Company in addressing the claim or circumstance for which you are incurring mitigation expenses.
- b. Your participation on the mitigation expenses are borne entirely by you and you will not obtain insurance to cover it.

**2. Class 1 Product Recall Expenses Reimbursement**

The Company will reimburse you for class 1 product recall expenses in excess of the class 1 product recall expenses deductible and subject to the class 1 product recall expenses sublimit of liability set forth in the Declarations provided that the class 1 product recall:

- a. takes place in the coverage territory;
- b. is initiated during the policy period;
- c. prior to the policy period, no executive officer had prior knowledge of any potential need for such class 1 product recall; and
- d. the Company provides written approval of any class 1 product recall expenses prior to such class 1 product recall expenses being incurred.

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**3. Medical Expenses**

The Company will reimburse you for medical expenses subject to the medical expenses limit of liability set forth in the Declarations for bodily injury caused by an accident that happens to a human subject in connection with the conduct of a clinical trial, provided that:

- a. the accident takes place during the policy period;
- b. the medical expenses are incurred by any Named Insured and reported to the Company within one year of the date of the accident;
- c. the injured medical test subject submits to examination, at the Company's expense, by physicians of the Company's choice as often as the Company reasonably requires; and
- d. such bodily injury is not otherwise excluded under the policy.

The Company will make these payments regardless of fault.

II) Section II. LIMITS OF LIABILITY AND DEDUCTIBLE OR RETENTION, D. Multiple Insureds, Claims and Claimants is deleted and replaced by:

**D. Multiple Insureds, Claims and Claimants**

The limits of liability shown in the Declarations are the amounts the Company will pay as damages, claim expenses, mitigation expenses, or class 1 product recall expenses regardless of the number of Insureds, claims made, circumstances reported, class 1 product recalls, or persons or entities making claims.

III) The following is added to Section II. LIMITS OF LIABILITY AND DEDUCTIBLE OR RETENTION of this policy:

**F. Supplementary Benefits Limits**

**1. Mitigation expenses Sublimit of Liability**

- a. **Sublimit of Liability—each claim or circumstance**  
Subject to paragraph b. below, the amount paid by the Company for mitigation expenses for each claim or circumstance shall not exceed the mitigation expenses sublimit for Each Claim or Circumstance set forth in the Declarations.
- b. **Sublimit of Liability—in the aggregate**  
The sublimit of liability of the Company for mitigation expenses for all claims or circumstances shall not exceed the amount set forth in the Declarations as the mitigation expenses Aggregate.

The mitigation expenses sublimits set forth in the Declarations are included within and are not in addition to the Products-Completed Operations Each Claim and Aggregate Liability limits as shown in the Declarations. As such, the mitigation expenses sublimits erode the Each Claim Products-Completed Operations Liability limit and the Products-Completed Operations Liability Aggregate limit of liability set forth in the Declarations. All mitigation expenses arising out of the same occurrence are subject to the applicable limits of liability of the policy where the first request for mitigation expenses is made.

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**2. Class 1 product recall expenses Sublimit of Liability**

**a. Sublimit of Liability—each claim or circumstance**

Subject to paragraph b. below, the amount paid by the Company for expenses for each class 1 product recall shall not exceed the class 1 product recall expenses sublimit for Each Recall set forth in the Declarations.

**b. Sublimit of Liability—in the aggregate**

The amount paid by the Company for expenses for all class 1 product recalls shall not exceed the amount set forth in the Declarations as the class 1 product recall expenses Aggregate.

The class 1 product recall expenses sublimits set forth in the Declarations are included within and are not in addition to the Products-Completed Operations Each Claim and Aggregate Liability limits as shown in the Declarations. As such, the class 1 product recall expenses sublimits erode the Each Claim Products-Completed Operations Liability limit and the Products-Completed Operations Liability Aggregate limit of liability set forth in the Declarations. All class 1 product recall expenses arising out of the same occurrence are subject to the applicable limits of liability of the policy where the first request for class 1 product recall expenses is made.

**3. Medical Expenses Sublimit of Liability**

**a. Limit of Liability—each person**

Subject to paragraph b. below, the limit of liability of the Company for all medical expenses for each injured test subject shall not exceed the medical expenses sublimit set forth in the Declarations.

**b. Limit of Liability—in the aggregate**

The limit of liability of the Company for all medical expenses in the aggregate shall not exceed the amount stated in the Declarations as the aggregate.

The Medical Expenses Limits are in addition to the each claim and all claims in the aggregate limits of liability set forth in the Declarations.

**IV) The following is added to Section III. EXCLUSIONS of this policy:**

**Class 1 Product Recall Expenses Exclusion:**

This policy does not apply to any class 1 product recall expenses due to:

**1. Caprice**

caprice or whim of any Insured;

**2. Chemical change**

deterioration, decomposition or transformation of a chemical nature, except if caused by an error in the design, manufacturing, processing, packaging, handling, distributing, labeling, storage or transportation of your product;

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3. **Faulty formula**

improper, inadequate or faulty formula or specifications, unless there is a reasonable probability that such improper, inadequate or faulty formula or specifications will cause **bodily injury or property damage**;

4. **Intended purpose**

failure of **your product** to accomplish its intended purpose, including any breach of warranty of fitness, quality, efficacy or efficiency, whether written or implied;

5. **Loss of reputation**

loss of reputation, customer faith or approval, or any costs incurred to regain customer market, or any other consequential damages;

6. **Prior circumstances**

any fact, **circumstance** or situation that at the inception of the **policy period** or the date **you** relinquished **your product** to others;

- a) was known to any **insured** or was reasonably foreseeable by any **insured**; and
- b) that would cause a reasonable person to believe a **class 1 product recall** would result;

7. **Redistribution or replacement**

redistribution or replacement of the withdrawn products by like products or substitutions;

8. **Shelf life**

**your product** exceeding its designated shelf life;

9. **Withdrawal of similar products**

the withdrawal of similar products or batches that are not defective, when a defect in another product or batch has been found.

V) The following is added to Section IV. **DEFINITIONS**, Claim expenses:

**Claim expenses do not include mitigation expenses.**

VI) In regards to **Class 1 product recall expense** coverage only, Section IV. **DEFINITIONS**, **Class 1 product recall** is deleted and replaced by:

**Class 1 product recall**

means that **you** or the United States Food and Drug Administration, or any foreign equivalent, have determined **your product** poses a situation in which there is a reasonable probability that the use of or exposure to **your product** will cause serious adverse health consequences or death, and as a result of that determination, **you** issue a recall for **your products** that had been manufactured, processed,

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packaged, handled, distributed, or sold by you, and physically relinquished to others. A **class 1 product recall** is deemed to be a **circumstance** and is subject to the reporting requirements of Section V., **CONDITIONS**, paragraph B. **Your Rights In The Event Of A Circumstance**.

VII) The following is added to Section IV. **DEFINITIONS**:

**Class 1 product recall expenses**

means reasonable and necessary expenses, incurred with the Company's prior written consent as a result of a **class 1 product recall**, for:

- A. any communication costs incurred to announce the withdrawal, including but not limited to:
  - 1. telephone, radio, television, and internet announcements; and
  - 2. production costs of the announcements, such as printing costs, stationary, envelopes and postage;
- B. transporting **your product** from any purchaser, distributor or user, to locations designated by **you**;
- C. transporting **your employees** to any purchaser, distributor or user in order to effectuate reasonable and necessary on-site repairs due to a **class 1 product recall**;
- D. remunerating **your employees** for overtime to perform the actions in 1. 2., or 3. above, and, if necessary, the cost to hire and pay additional persons other than **your** regular employees to perform these actions;
- E. properly disposing of **your product**, including packaging that cannot be reused; or
- F. renting temporary locations used to store **your product**.

However, **class 1 product recall expenses** do not include **mitigation expenses** or **medical expenses**.

**Mitigation expenses**

means reasonable and necessary fees, costs and expenses incurred by you in **your** efforts to mitigate potential **damages** for which **you** might become liable due to a claim or a **circumstance**. **Mitigation expenses** do not include fees, costs or expenses incurred to comply with any governmental or regulatory requirement, **class 1 product recall expenses** or **medical payments**. **Mitigation expenses** do not include **damages** or **claim expenses**.

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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## NEW JERSEY AMENDATORY ENDORSEMENT

### THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

**GLS Elite Products-Completed Operations Liability Coverage**

**GLS Elite Products-Completed Operations And Professional Liability Coverage**

Section V. CONDITIONS, J. Cancellation, is deleted in its entirety and replaced with the following:

#### J. Cancellation/Non-Renewal

1. Pursuant to New Jersey law, this Policy cannot be cancelled or non-renewed for any underwriting reason or guideline which is arbitrary, capricious or unfairly discriminatory or without adequate prior notice to the insured. The underwriting reasons or guidelines that an insurer can use to cancel or non-renew this Policy are maintained by the insurer in writing and will be furnished to the Insured and/or the Insured's lawful representative upon written request.

This provision shall not apply to any policy which has been in effect for less than 60 days at the time notice of cancellation is mailed or delivered, unless the policy is a renewal policy.

#### 2. Cancellation

- a. This Policy of insurance may be cancelled by the **First Named Insured** by surrender thereof to the Company or by mailing to the Company written notice stating when thereafter the cancellation shall be effective.
- b. If this Policy has been effect for less than 60 days, the Company may cancel this Policy at any time by mailing to the **First Named Insured** and any person entitled to notice under this Policy, written notice of cancellation at least:
  - i. 10 days before the effective date of cancellation if the Policy is cancelled for nonpayment of premium; or
  - ii. 30 days before the effective date of cancellation for any other reason.
- c. If this Policy has been in effect for 60 days or more, or is a renewal of a Policy the Company issued, this Policy may be cancelled by the Company only for one or more of the following reasons:
  - i. Nonpayment of premium;
  - ii. Existence of a moral hazard, as defined in N.J.A.C. 11:1-20.1(f);
  - iii. Material misrepresentation or nondisclosure to the Company of a material fact at the time of acceptance of the risk;
  - iv. Increased hazard or material change in the risk assumed which the Company could not have reasonably contemplated at the time of assumption of the risk;

- v. Substantial breaches of contractual duties, conditions or warranties that materially affect the nature and/or insurability of the risk;
  - vi. Lack of cooperation from the **Named Insured** on loss control matters materially affecting insurability of the risk;
  - vii. Fraudulent acts against the Company by the **Named Insured** or their representative that materially affect the nature of the risk insured;
  - viii. Loss of or reduction in available insurance capacity;
  - ix. Material increase in exposure arising out of changes in statutory or case law subsequent to the issuance of the Policy or any subsequent renewal;
  - x. Loss of or substantial changes in applicable reinsurance;
  - xi. Failure by the **Named Insured** to comply with any federal, state or local fire, health, safety or building or construction regulation, law or ordinance with respect to an insured risk which substantially increases any hazard insured against within 60 days of written notification of a violation of any such law, regulation or ordinance;
  - xii. Failure by the **Named Insured** to provide reasonable and necessary underwriting information to the Company upon written request therefore and a reasonable opportunity to respond;
  - xiii. Agency termination, provided:
    - (a) The Company documents that replacement coverage at comparable rates and terms has been provided to the **First Named Insured**, and the Company has informed the **First Named Insured**, in writing, of the right to continue coverage with the Company; or
    - (b) The Company has informed the **First Named Insured**, in writing, of the right to continue coverage with the Company and the **First Named Insured** has agreed, in writing, to the cancellation or non-renewal based on the termination of their appointed agent.
  - xiv. Any other reasons in accordance with our underwriting guidelines for cancellation of commercial lines coverage.
- d. If this Policy is cancelled by the Company based on reason c.i. or c.ii. above, the Company shall mail a written notice of cancellation, stating the reason for cancellation, to the **First Named Insured** and any person entitled to notice under this Policy at least 10 days before the effective date of cancellation. For cancellation due to the nonpayment of a premium, the notice shall state the effect of nonpayment by the due date. Cancellation for nonpayment of premium shall not be effective if payment of the amount due is made prior to the effective date set forth in the notice. If this Policy is cancelled for any other reason listed above, the Company shall mail a written notice of cancellation, stating the reason for cancellation to the **First Named Insured** and any person entitled to notice under this Policy, not more than 120 days nor less than 30 days before the effective date of such cancellation.
- e. The notice of cancellation shall be sent:
- i. By certified mail; or
  - ii. By first class mail, if the Company has obtained from the post office a date stamped proof of mailing showing names and addresses.
- f. The Company is not required to provide notice of cancellation if the **First Named Insured** has:

- i. Replaced coverage elsewhere; or
    - ii. Specifically requested termination.
  - g. If the **First Named Insured** cancels this Policy, earned premium shall be computed in accordance with the customary short rate table and procedure. If the Company cancels this Policy, earned premium shall be computed pro rata. Premium adjustment may be made either at the time cancellation is effected or as soon as practicable after cancellation becomes effective, but payment or tender of unearned premium is not a condition of cancellation.
3. Non-Renewal
- a. The Company may elect not to renew this Policy for any reason permitted to cancel it. If the Company elects not to renew this Policy, the Company shall mail a notice of non-renewal, stating the reasons for non-renewal, to the **First Named Insured** at least 30 days but not more than 120 days before the expiration date of this Policy. If this Policy does not have a fixed expiration date, it shall be deemed to expire annually on the anniversary of its inception.
  - b. This notice will be sent to the **First Named Insured** at the last mailing address known to the Company by:
    - i. Certified mail; or
    - ii. First class mail, if the Company has obtained from the post office a date stamped proof of mailing showing the **First Named Insured's** name and address.
  - c. The Company need not mail or deliver this notice if the **First Named Insured** has:
    - i. Replaced coverage elsewhere; or
    - ii. Specifically requested termination.

All other terms and conditions of this Policy remain unchanged.



**THIS ENDORSEMENT CHANGES THE POLICY.  
PLEASE READ IT CAREFULLY.**

**DESIGNATED PRODUCTS EXCLUSION**

This endorsement modifies insurance provided under the following:  
GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE POLICY

The following is added to **SECTION III. EXCLUSIONS**:

**Excluded Products**

based on or arising out of:

- 1) the manufacturing of, or sponsoring of clinical trials involving, the following products or any products made of or containing any of the following:
  - Any product containing mercury, where such product is intended to be implanted, ingested, injected, inhaled or absorbed
  - Birth control or fertility goods or products whose primary function is to control or affect fertility, fertilization, conception or contraception
  - Di-(2-Ethylhexyl) Phthalate (DEHP) used in goods or products approved for neonatal patients
  - Diethylstilbestrol (DES)
  - Ephedra
  - Ephedrine, or pseudoephedrine, except where used in Over the Counter or prescription products
  - Fentanyl or fentanyl patches, except for generics manufactured after addition of the warnings for opioid addiction and Serotonin Syndrome to the labeling
  - Isotretinoin
  - Latex gloves when sensitivity warning is not on package or other labeling
  - Live virus vaccines, except for attenuated vaccines
  - Metoclopramide (including but not limited to Reglan) in regards to side effects of Tardive Dyskinesia, worsening of Parkinson's, and other movement disorders resulting from usage of the drug,
  - Oral hormone replacement products approved for menopause treatment
  - Pain pumps when inserted directly into an orthopedic joint and administering pharmaceuticals not approved for joint application
  - Permanent breast implants, except when part of mastectomy reconstruction products
  - Phentermine used in combination with fenfluramine (including but not limited to Pondimin) or dexfenfluramine (Redux)
  - Propoxyphene (including but not limited to Darvon or Darvocet)
  - Selective Serotonin Reuptake Inhibitors (SSRI), except for generic manufactured after addition of the warnings to labeling for increased suicide risk and increased birth defect risk if used by pregnant women
  - Vaccines with preservatives approved for persons under age of 18
- 2) blood banks and blood donation facilities, except biobanks storing samples for research and development

The exclusions above shall not apply to contract manufacturers who are indemnified and held harmless contractually, or do not have responsibility for label or warning design, regulatory reporting, safety surveillance, formulation or development.

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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**THIS ENDORSEMENT CHANGES THE POLICY.  
PLEASE READ IT CAREFULLY.**

**SPECIFIED ADDITIONAL INSURED ENDORSEMENT**

This endorsement modifies insurance provided under the following:

GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE

GLS ELITE PRODUCTS-COMPLETED AND PROFESSIONAL LIABILITY COVERAGE

Section IV. **DEFINITIONS**, **Insured** is amended to include as an additional **Insured** any person(s) or organization(s) (referred to below) shown in the Schedule:

Additional Insured(s):

Wells Fargo bank, National Association, as Agent & its successors and/or Assigns.

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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**THIS ENDORSEMENT CHANGES THE POLICY.  
PLEASE READ IT CAREFULLY.**

**ADDITIONAL NAMED INSURED(S) ENDORSEMENT**

This endorsement modifies insurance provided under the following:  
GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE  
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

It is agreed that Section **IV. DEFINITIONS**, **Named Insured** is amended to include the following persons or entities listed in the schedule below as **Named Insureds** in the Declarations of this policy.

**SCHEDULE**

1. Pernix Therapeutics Holdings, Inc.
2. Cypress Pharmaceuticals, Inc.
3. Gaine, Inc.
4. GTA GP, Inc.
5. GTA LP, Inc.
6. Hawthorn Pharmaceuticals, Inc.
7. Macoven Pharmaceuticals, LLC
8. Pernix Manufacturing, LLC
9. Pernix Manufacturing, LLC dba Great Southern Laboratories
10. Pernix Sleep, Inc. dba Somaxon Pharmaceuticals Inc.
11. Pernix Therapeutics, LLC
12. Respicopea, Inc.
13. Respicopea, Limited
14. Zinterests, LLC
15. Pernix Ireland, Ltd fka Worrigan Limited
16. Pernix Ireland Pain fka Ferrimill Ltd.

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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**THIS ENDORSEMENT CHANGES THE POLICY.  
PLEASE READ IT CAREFULLY.**

**SCHEDULE OF RETRO DATES ENDORSEMENT**

This endorsement modifies insurance provided under the following:  
GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE  
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

It is hereby agreed that Item 7. of the Declarations page, Retroactive Date, is amended to read as follows:

|             |   |
|-------------|---|
| 08/20/2014: | Treximet  |
| 10/25/2013: | Zohydro ER but only for this product sold by the named insured after 4/25/2015, from inventory acquired on 4/25/2015 and controlled by the named insured. |
| 02/18/2000: | All Other Products  |

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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**THIS ENDORSEMENT CHANGES THE POLICY  
PLEASE READ IT CAREFULLY**

**PERNIX THERAPEUTICS HOLDINGS, INC.  
MANUSCRIPT ENDORSEMENT**

1. Section III. **EXCLUSIONS**, B. **Assumed Liability** is deleted and replaced with the following:

**B. Assumed Liability**

based on or arising out of any actual or alleged:

1. **bodily injury, property damage; or**
2. **personal and advertising injury,**

for which any Insured is obligated to pay damages by reason of the assumption of liability in a contract or agreement.

This exclusion does not apply to liability for damages:

- a. for which an Insured would have been liable in the absence of the contract or agreement or related agreement; or
- b. assumed in a contract or agreement that is an insured contract, provided the **bodily injury, property damage or personal and advertising injury**, occurs subsequent to the execution of the contract or agreement. Solely for the purposes of liability assumed in an insured contract, reasonable attorney fees and necessary litigation expenses incurred by or for a party other than an Insured are deemed to be part of claim expenses because of **bodily injury, property damage, or personal and advertising injury** provided:
  - i. liability to such party for, or for the cost of, that party's defense has also been assumed in the same insured contract; and
  - ii. such attorney fees and litigation expenses are for defense of that party against a civil action or alternative dispute resolution proceeding in which damages to which this insurance applies are alleged.

2. The following is added to Section III. **EXCLUSIONS**:

**New Products, Acquisition and Label Changes**

any actual or alleged **bodily injury or property damage** based on or arising out of:

1. any new product sold or tested by you or others on your behalf;
2. the testing in clinical trial for a new indication; or
3. the sale of existing products for a new indication.

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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Solely for the purposes of this exclusion:

1. new product is defined as a product first acquired, or approved for sale by the FDA, after the effective date of this Policy;
2. new indication is defined as a novel, new or additional authorization to market for a new disease state, new population, or new health condition which will require a revision of the Instructions for Use of the product(s).

This exclusion will not apply if documentation regarding the new product, new testing, or new indication is provided at least 30 days prior to the commencement of the new testing or the sale of the new product or indication, and written approval has been provided by the Company or an endorsement to this Policy is issued.

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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**THIS ENDORSEMENT CHANGES THE POLICY.  
PLEASE READ IT CAREFULLY.**

**FULL TERRORISM EXCLUSION (INCLUDING CERTIFIED ACT OF  
TERRORISM)**

This endorsement modifies insurance provided under the following:  
GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE

1. The following is added to Section III. EXCLUSIONS:

**Terrorism**

based on or arising, directly or indirectly, out of any act of terrorism, including, but not limited to, a **certified act of terrorism**, regardless of any other cause or event that contributes concurrently or in any sequence to the claim, injury or loss.

2. The following is added to Section IV. DEFINITIONS:

**Certified act of terrorism** means an act that is certified by the Secretary of the Treasury, to be an act of terrorism pursuant to the federal Terrorism Risk Insurance Act. The criteria contained in the Terrorism Risk Insurance Act for a **certified act of terrorism** include the following:

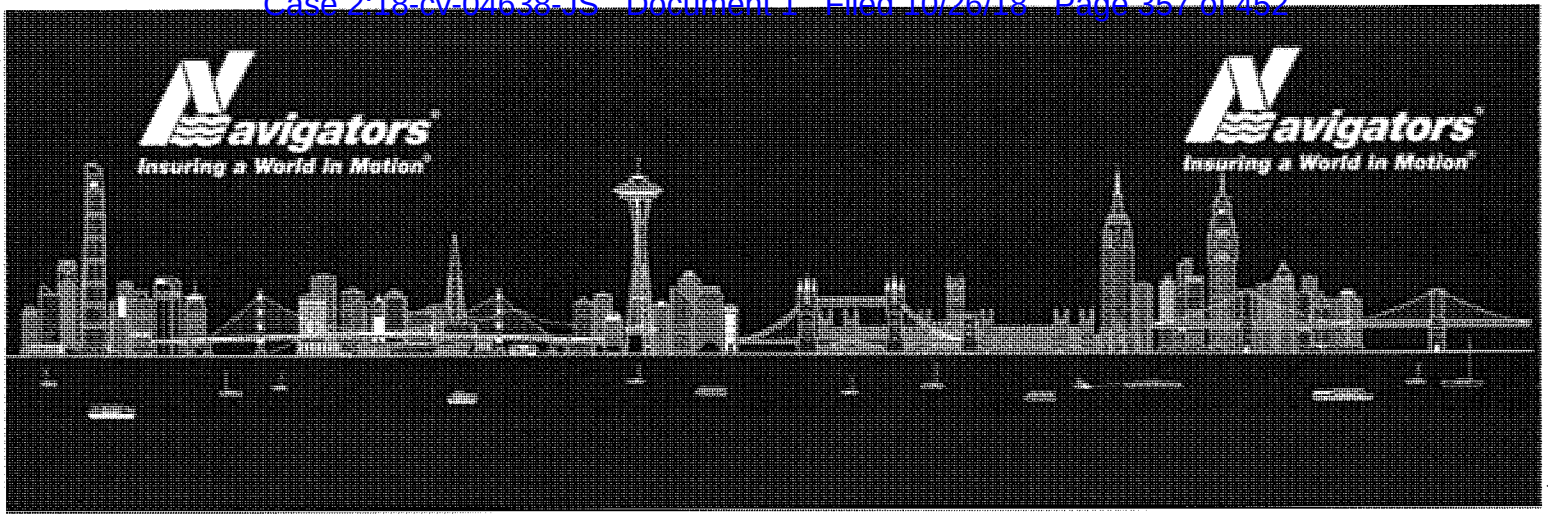
1. The act resulted in insured losses in excess of \$5 million in the aggregate, attributable to all types of insurance subject to the Terrorism Risk Insurance Act; and
2. The act is a violent act or an act that is dangerous to human life, property or infrastructure and is committed by an individual or individuals as part of an effort to coerce the civilian population of the United States or to influence the policy or affect the conduct of the United States Government by coercion.

**ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.**

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# **EXHIBIT E**





# NavStar

## Navigators Insurance Company

A "Stock" Company

One Penn Plaza, New York, New York 10119

NSI 80 01 08 16

Insured Copy

NAVIGATORS INSURANCE COMPANY

Policy/Quote Number: CH17NCP020480-00

Insured Name: PERNIX THERAPEUTICS HOLDINGS I  
 Insured Address: 10 NORTH PARK PLACE  
 SUITE 201  
 MORRISTOWN, NJ 07960  
 USA

## POLICYHOLDER DISCLOSURE NOTICE OF TERRORISM INSURANCE COVERAGE

You are hereby notified that under the Terrorism Risk Insurance Act (the Act), as amended, you have a right to purchase insurance coverage for losses resulting from acts of terrorism, as defined in Section 102(1) of the Act. The term "act of terrorism" means any act or acts that are certified by the Secretary of the Treasury, in consultation with the Secretary of Homeland Security, and the Attorney General of the United States - to be an act of terrorism; to be a violent act or an act that is dangerous to human life, property, or infrastructure; to have resulted in damage within the United States, or outside the United States in the case of an air carrier or vessel or the premises of a United States mission; and to have been committed by an individual or individuals as part of an effort to coerce the civilian population of the United States or to influence the policy or affect the conduct of the United States Government by coercion.

YOU SHOULD KNOW THAT WHERE COVERAGE IS PROVIDED BY THIS POLICY FOR LOSSES RESULTING FROM CERTIFIED ACTS OF TERRORISM, SUCH LOSSES MAY BE PARTIALLY REIMBURSED BY THE UNITED STATES GOVERNMENT UNDER A FORMULA ESTABLISHED BY FEDERAL LAW. HOWEVER, YOUR POLICY MAY CONTAIN OTHER EXCLUSIONS WHICH MIGHT AFFECT YOUR COVERAGE, SUCH AS AN EXCLUSION FOR NUCLEAR EVENTS. UNDER THE FORMULA, THE UNITED STATES GOVERNMENT GENERALLY REIMBURSES 85% THROUGH 2015; 84% BEGINNING ON JANUARY 1, 2016; 83% BEGINNING ON JANUARY 1, 2017; 82% BEGINNING ON JANUARY 1, 2018; 81% BEGINNING ON JANUARY 1, 2019 AND 80% BEGINNING ON JANUARY 1, 2020, OF COVERED TERRORISM LOSSES EXCEEDING THE STATUTORILY ESTABLISHED DEDUCTIBLE PAID BY THE INSURANCE COMPANY PROVIDING THE COVERAGE. THE PREMIUM TO BE CHARGED FOR THIS COVERAGE IS PROVIDED BELOW AND DOES NOT INCLUDE ANY CHARGES FOR THE PORTION OF LOSS THAT MAY BE COVERED BY THE FEDERAL GOVERNMENT UNDER THE ACT.

YOU SHOULD ALSO KNOW THAT THE TERRORISM RISK INSURANCE ACT, AS AMENDED, CONTAINS A \$100 BILLION CAP THAT LIMITS U.S. GOVERNMENT REIMBURSEMENT AS WELL AS INSURERS' LIABILITY FOR LOSSES RESULTING FROM CERTIFIED ACTS OF TERRORISM WHEN THE AMOUNT OF SUCH LOSSES IN ANY ONE CALENDAR YEAR EXCEEDS \$100 BILLION. IF THE AGGREGATE INSURED LOSSES FOR ALL INSURERS EXCEED \$100 BILLION, YOUR COVERAGE MAY BE REDUCED.

### SELECTION OR REJECTION OF TERRORISM INSURANCE COVERAGE

The prospective premium required for your terrorism coverage is: \$332

If you wish to reject this offer of coverage, you should check the box below, sign this notice and send it to your agent. An exclusion of terrorism losses, as defined by the Act, will then be made part of your policy.

☐ I hereby reject the offer of terrorism coverage. I understand that I will have no coverage for losses arising from acts of terrorism, as defined in the act.

If your policy includes Property Coverage in one or more of these states: CA, CT, GA, HI, IA, IL, MA, ME, MO, NC, NJ, NY, OR, RI, VA, WA, WI or WV, the following statement applies:

The terrorism exclusion makes an exception for (and thereby continues your coverage for) property fire losses resulting from an act of terrorism. Therefore, if you reject the offer of terrorism coverage, that rejection does not apply to fire losses resulting from an act of terrorism - the coverage in your policy for

PHN 001 IL 03 16

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 Insurance Commissioners, with its permission.

Page 1 of 2

such fire losses will continue. If such a loss occurs, and is certified under the Act, the loss will be reimbursed by the United States Government under the formula detailed above.

The portion of your policy premium attributable to terrorism (fire only) coverage in all of the states listed above, is Mandatory even when TRIA is rejected. This amount is included in your policy premium and cannot be rejected. The return premium resulting from a rejection of TRIA will still generate this premium, which is a percentage of the total premium noted above. The difference will be reflected in actual premium return resulting from a rejection of TRIA compared to the total premium noted above.

If your policy includes Inland Marine Coverage in one or more of these states: CA, ME, MO, OR or WI, the following statement applies:

The terrorism exclusion makes an exception for (and thereby continues your coverage for) direct property damage fire losses resulting from an act of terrorism. Therefore, if you reject the offer of terrorism coverage, that rejection does not apply to direct property damage fire losses resulting from an act of terrorism - the coverage in your policy for such fire losses will continue. If such a loss occurs, and is certified under the Act, the loss will be reimbursed by the United States under the formula detailed above.

In all of the states listed above in which your policy provides Inland Marine coverage, the portion of your Inland Marine policy premium attributable to coverage for direct property damage from fire resulting from terrorism is Mandatory and even when TRIA is rejected. This amount is included in your policy premium and cannot be rejected. The return premium resulting from a rejection of TRIA will still generate this premium, which is a percentage of the total premium noted above. The difference will be reflected in actual premium return resulting from a rejection of TRIA compared to the total premium noted above.

\_\_\_\_\_  
Policyholder/Applicant's Signature

\_\_\_\_\_  
Navigators Insurance Company  
Insurance Company

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

If you have any questions about this notice, please contact your agent.

## Policyholder Notice



### CLAIM REPORTING PROCEDURES

Conditions of the policy require that in the event of a claim, you notify us as soon as practicable. All Claim notifications are to be reported to the office by electronic mail to [newloss@navg.com](mailto:newloss@navg.com).

**If you are reporting an auto claim, please send your claim notification to [7362NAVS@yorkrsg.com](mailto:7362NAVS@yorkrsg.com).**

In the alternative, claim notices may also be:

- Mailed to the Danbury Office at:

Navigators Management Co. Inc.  
Claims Division  
83 Wooster Heights Road  
Danbury, CT 06810

- Or faxed to 847-285-9003
- Or reported to our 24 hour call center at 855-444-4796

All claim notifications must be accompanied by an ACORD loss form and should contain current contact information for the insured and claimant(s) as well as a detailed description of the loss.

If the insured files a claim with the agent, it is the agent's responsibility to forward the claim to the Danbury Office.



**Policy Number**  
**CH17NCP020480-00**

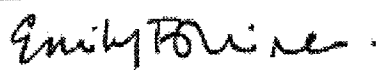
**COMMON POLICY DECLARATIONS**

**NAVIGATORS INSURANCE COMPANY**  
**A "Stock" Company**  
**One Penn Plaza, New York, NY 10119**  
**(212) 244-2333**

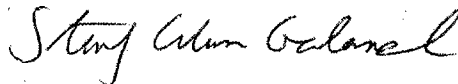
|                |  |  |
|----------------|--|--|
| <b>Item 1.</b> | <b>Named Insured and Mailing Address</b>   | <b>Agent Name and Address</b>  |
|                | PERNIX THERAPEUTICS HOLDINGS<br>(SEE NAMED INSURED ENDT)<br>10 NORTH PARK PLACE<br>SUITE 201<br>MORRISTOWN NJ 07960  | CONNER STRONG COMPANIES<br>50 S 16TH STREET<br>SUITE 3600<br>PHILADELPHIA PA 19102 |
|                |  | Agent No. CONN0358   |
| <b>Item 2.</b> | <b>Policy Period</b>   | <b>From: 11-30-2017 To: 11-30-2018</b>   |
|                | <b>at 12:01 A.M., Standard Time at your mailing address shown above.</b>   |  |
| <b>Item 3.</b> | <b>Business Description:</b>   |  |
|                | Form of Business: CORPORATION  |  |
| <b>Item 4.</b> | In return for the payment of the premium, and subject to all the terms of this policy, we agree with you to provide the insurance as stated in this policy.                        |  |
|                | This policy consists of the following coverage parts for which a premium is indicated. Where no premium is shown, there is no coverage. This premium may be subject to adjustment. |  |
|                | <b>Coverage Part(s)</b>  | <b>Premium</b>   |
|                | Commercial Property Coverage Part  | NOT COVERED  |
|                | Commercial General Liability Coverage Part   | \$ 33,483.00   |
|                | Crime and Fidelity Coverage Part   | NOT COVERED  |
|                | Commercial Inland Marine Coverage Part   | NOT COVERED  |
|                | Commercial Auto (Business or Motor Carrier) Coverage Part  | NOT COVERED  |
|                | Commercial Garage / Auto Dealers Coverage Part   | NOT COVERED  |
|                |  |  |
|                |  |  |
|                |  |  |
|                | TAX OR SURCHARGE   | \$ 198.91  |
|                | Total Policy Premium   | \$ 33,681.91   |
| <b>Item 5.</b> | <b>Forms and Endorsements</b>  |  |
|                | Form(s) and Endorsement(s) made a part of this policy at time of issue:  |  |
|                | <b>See Schedule of Forms and Endorsements</b>  |  |

THIS COMMON POLICY DECLARATION AND THE SUPPLEMENTAL DECLARATION(S), TOGETHER WITH THE COMMON POLICY CONDITIONS, COVERAGE PART(S), COVERAGE FORM(S) AND FORMS AND ENDORSEMENTS, IF ANY, COMPLETE THE ABOVE NUMBERED POLICY.

**In Witness Whereof**, the issuing Company has caused this policy to be signed officially below and countersigned on the Declarations page by a duly authorized representative of said Company.

  
\_\_\_\_\_

[Emily Miner]  
Secretary

  
\_\_\_\_\_

[Stanley A. Galanski]  
President

---

Navigators Insurance Company

NAV-SIG-001 (10/10)

Insured Copy



Policy Number  
CH17NCP020480-00

SCHEDULE OF NAMED INSURED(S)

NAVIGATORS INSURANCE COMPANY

Named Insured    PERNIX THERAPEUTICS HOLDINGS

Effective Date:    11-30-17  
12:01 A.M., Standard Time

Agent Name        CONNER STRONG COMPANIES

Agent No.         CONN0358

NAV-CO-DEC    (cont.)

THE NAMED INSURED ON FORM NAV-CO-DEC IS AMENDED TO READ:

PERNIX THERAPEUTICS HOLDINGS  
INC  
CYPRESS PHARMACEUTICALS, INC  
GAINE, INC  
GTA GP, INC  
GTA LP, INC  
HAWTHORN PHARMACEUTICALS, INC  
MACOVEN PHARMACEUTICALS, LLC  
PERNIX MANUFACTURING, LLC  
PERNIX MANUFACTURING, LLC DBA  
GREAT SOUTHERN LABORATORIES  
PERNIX THERAPEUTICS, LLC  
RESPICOPEA, INC  
RESPICOPEA, LIMITED  
PERNIX SLEEP INC. DBA SOMAXON  
PHARMACEUTICALS, INC  
ZINTERESTS, LLC  
PERNIX IRELAND LTD F/K/A  
WORRIGAN LIMITED  
PERNIX IRELAND PAIN, LIMITED  
F/K/A FERRIMILL LTD



Policy Number  
CH17NCP020480-00

SCHEDULE OF TAXES, SURCHARGES OR FEES  
NAVIGATORS INSURANCE COMPANY

Named Insured    PERNIX THERAPEUTICS HOLDINGS

Effective Date:    11-30-17  
12:01 A.M., Standard Time

Agent Name        CONNER STRONG COMPANIES

Agent No.         CONN0358

CO-DEC (cont.)

TAXES/SURCHARGES DETAILED BREAKDOWN :

|                        |    |        |
|------------------------|----|--------|
| NJ-PLIGA SURCHARGE     | \$ | 198.91 |
|                        |    | -----  |
| TOTAL TAXES/SURCHARGES | \$ | 198.91 |





**Policy Number**  
**CH17NCP020480-00**

**SCHEDULE OF FORMS AND ENDORSEMENTS**

**NAVIGATORS INSURANCE COMPANY**

**Named Insured**     PERNIX THERAPEUTICS HOLDINGS

**Effective Date:**     11-30-17  
12:01 A.M., Standard Time

**Agent Name**     CONNER STRONG COMPANIES

**Agent No.**     CONN0358

**COMMON POLICY FORMS AND ENDORSEMENTS**

|                |       |  |
|----------------|-------|--|
| NSI 80 01      | 08-16 | NAVSTAR POLICY JACKET                    |
| PHN 001 IL     | 03-16 | POLICYHOLDER DISCLOSURE NOTICE OF TERROR |
| NAV-PHN-MM-200 | 04-17 | CLAIM REPORTING PROCEDURES               |
| NAV-CO-DEC     | 12-15 | COMMON POLICY DECLARATIONS               |
| NAV-SIG-001    | 10-10 | NAV SIGNATURE PAGE                       |
| NI-SCHED       | 01-97 | SCHEDULE OF NAMED INSURED(S)             |
| TAX-FORM       | 01-97 | SCHEDULE OF TAXES, SURCHARGES OR FEES    |
| FORM-SCHED     | 01-97 | SCHEDULE OF FORMS AND ENDORSEMENTS       |
| LOC-SCHED      | 01-97 | SCHEDULE OF LOCATIONS                    |
| NAV-ML-002     | 11-12 | OFAC ENDORSEMENT                         |
| IL 00 21       | 09-08 | NUCLEAR ENERGY LIABILITY EXCLUSION ENDT  |
| NSI 00 01      | 10-15 | COMMON POLICY CONDITIONS                 |
| NSI 50 02      | 10-15 | AMENDMENT OF CONDITIONS CANCELLATION     |
| IL 01 41       | 09-08 | NEW JERSEY CHANGES - CIVIL UNION         |
| IL 02 08       | 09-07 | NJ CHANGES-CANC & NONRENL                |

**GENERAL LIABILITY FORMS AND ENDORSEMENTS**

|              |       |   |
|--------------|-------|---|
| GL-DEC       | 12-01 | COMM GENERAL LIABILITY COVERAGE SUPP DEC        |
| NAV-GL-SCHED | 01-16 | COMM GENERAL LIABILITY COVERAGE SCHEDULE        |
| CG 00 01     | 04-13 | COMMERCIAL GENERAL LIABILITY COV FORM           |
| NSG 10 01    | 10-15 | POLARIS A-GENERAL LIABILITY EXTENSION           |
| NSG 20 02    | 10-15 | EXCLUSION - ASBESTOS                            |
| NSG 20 08    | 10-15 | RESTRICTION OF COVERAGE-LIFE SCIENCES           |
| NSG 20 10    | 10-15 | EXCLUSION-PROFESSIONAL SERVICES LIAB            |
| CG 20 26     | 04-13 | ADDL INSD-DESIGNATED PERSON/ORGANIZATION        |
| CG 21 04     | 11-85 | EXCL-PRODUCTS/COMPLETED OPER HAZARD             |
| CG 21 06     | 05-14 | EXCL-ACC/DISCL OF CONFIDENTIAL OR PERSONAL INFO |
| CG 21 47     | 12-07 | EMPLOYMENT-RELATED PRACTICES EXCLUSION          |
| CG 21 65     | 12-04 | TOTAL POLLUTION EXCL-WITH EXCEPTIONS            |
| CG 21 67     | 12-04 | FUNGI OR BACTERIA EXCLUSION                     |
| CG 26 20     | 10-93 | NJ CHANGES - LOSS INFORMATION                   |



**Policy Number**  
**CH17NCP020480-00**

**SCHEDULE OF LOCATIONS**

**NAVIGATORS INSURANCE COMPANY**

**Named Insured**     PERNIX THERAPEUTICS HOLDINGS

**Effective Date:**     11-30-17  
 12:01 A.M., Standard Time

**Agent Name**     CONNER STRONG COMPANIES

**Agent No.**     CONN0358

| Loc.<br>No. | Bldg.<br>No. | Designated Locations<br>(Address, City, State, Zip Code) | Occupancy |
|-------------|--------------|--|-----------|
| 001         | 001          | 10 NORTH PARK PLACE STE 201, MORRISTOWN, NJ<br>07960     |           |

**LOC-SCHED (01/97)**

## **OFAC ENDORSEMENT**

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

### **U.S. ECONOMIC AND TRADE SANCTIONS LIMITATIONS CLAUSE**

No insurer shall be deemed to provide cover and no insurer shall be liable to pay any claim or provide any benefit hereunder to the extent that the provision of such cover, payment of such claim or provision of such benefit would expose that insurer to any sanction, prohibition or restriction under the trade or economic sanctions, laws or regulations of the United States of America.

The United States of America trade or economic sanctions, laws or regulations shall include, but not be limited to, those sanctions administered and enforced by the U.S. Treasury Department's Office of Foreign Assets Control (OFAC).

All other terms, conditions and exclusions of this Policy remain unchanged.

IL 00 21 09 08

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

## NUCLEAR ENERGY LIABILITY EXCLUSION ENDORSEMENT

(Broad Form)

This endorsement modifies insurance provided under the following:

COMMERCIAL AUTOMOBILE COVERAGE PART  
COMMERCIAL GENERAL LIABILITY COVERAGE PART  
FARM COVERAGE PART  
LIQUOR LIABILITY COVERAGE PART  
MEDICAL PROFESSIONAL LIABILITY COVERAGE PART  
OWNERS AND CONTRACTORS PROTECTIVE LIABILITY COVERAGE PART  
POLLUTION LIABILITY COVERAGE PART  
PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE PART  
RAILROAD PROTECTIVE LIABILITY COVERAGE PART  
UNDERGROUND STORAGE TANK POLICY

**1. The insurance does not apply:**

**A. Under any Liability Coverage, to "bodily injury" or "property damage":**

- (1) With respect to which an "insured" under the policy is also an insured under a nuclear energy liability policy issued by Nuclear Energy Liability Insurance Association, Mutual Atomic Energy Liability Underwriters, Nuclear Insurance Association of Canada or any of their successors, or would be an insured under any such policy but for its termination upon exhaustion of its limit of liability; or
- (2) Resulting from the "hazardous properties" of "nuclear material" and with respect to which (a) any person or organization is required to maintain financial protection pursuant to the Atomic Energy Act of 1954, or any law amendatory thereof, or (b) the "insured" is, or had this policy not been issued would be, entitled to indemnity from the United States of America, or any agency thereof, under any agreement entered into by the United States of America, or any agency thereof, with any person or organization.

**B. Under any Medical Payments coverage, to expenses incurred with respect to "bodily injury" resulting from the "hazardous properties" of "nuclear material" and arising out of the operation of a "nuclear facility" by any person or organization.**

**C. Under any Liability Coverage, to "bodily injury" or "property damage" resulting from "hazardous properties" of "nuclear material", if:**

- (1) The "nuclear material" (a) is at any "nuclear facility" owned by, or operated by or on behalf of, an "insured" or (b) has been discharged or dispersed therefrom;
- (2) The "nuclear material" is contained in "spent fuel" or "waste" at any time possessed, handled, used, processed, stored, transported or disposed of, by or on behalf of an "insured"; or
- (3) The "bodily injury" or "property damage" arises out of the furnishing by an "insured" of services, materials, parts or equipment in connection with the planning, construction, maintenance, operation or use of any "nuclear facility", but if such facility is located within the United States of America, its territories or possessions or Canada, this exclusion (3) applies only to "property damage" to such "nuclear facility" and any property thereat.

**2. As used in this endorsement:**

"Hazardous properties" includes radioactive, toxic or explosive properties.

"Nuclear material" means "source material", "special nuclear material" or "by-product material".

"Source material", "special nuclear material", and "by-product material" have the meanings given them in the Atomic Energy Act of 1954 or in any law amendatory thereof.

"Spent fuel" means any fuel element or fuel component, solid or liquid, which has been used or exposed to radiation in a "nuclear reactor".

"Waste" means any waste material **(a)** containing "by-product material" other than the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its "source material" content, and **(b)** resulting from the operation by any person or organization of any "nuclear facility" included under the first two paragraphs of the definition of "nuclear facility".

"Nuclear facility" means:

- (a)** Any "nuclear reactor";
- (b)** Any equipment or device designed or used for **(1)** separating the isotopes of uranium or plutonium, **(2)** processing or utilizing "spent fuel", or **(3)** handling, processing or packaging "waste";

- (c)** Any equipment or device used for the processing, fabricating or alloying of "special nuclear material" if at any time the total amount of such material in the custody of the "insured" at the premises where such equipment or device is located consists of or contains more than 25 grams of plutonium or uranium 233 or any combination thereof, or more than 250 grams of uranium 235;

- (d)** Any structure, basin, excavation, premises or place prepared or used for the storage or disposal of "waste";

and includes the site on which any of the foregoing is located, all operations conducted on such site and all premises used for such operations.

"Nuclear reactor" means any apparatus designed or used to sustain nuclear fission in a self-supporting chain reaction or to contain a critical mass of fissionable material.

"Property damage" includes all forms of radioactive contamination of property.

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## COMMON POLICY CONDITIONS

### A. Cancellation

1. The first Named Insured shown in the Declarations may cancel this policy by mailing or delivering to us advance written notice of cancellation.
2. We may cancel this policy by mailing or delivering to the first Named Insured written notice of cancellation at least:
  - a. 10 days before the effective date of cancellation if we cancel for nonpayment of premium; or
  - b. 30 days before the effective date of cancellation if we cancel for any other reason.
3. We will mail or deliver our notice to the first Named Insured's last mailing address known to us.
4. Notice of cancellation will state the effective date of cancellation. The policy period will end on that date.
5. If this policy is cancelled, we will send the first Named Insured any premium refund due. If we cancel, the refund will be pro rata. If the first Named Insured cancels, the refund may be less than pro rata. The cancellation will be effective even if we have not made or offered a refund.
6. If notice is mailed, proof of mailing will be sufficient proof of notice.

### B. When We Do Not Renew

If we decide not to renew this Coverage Part, we will mail or deliver to the first Named Insured shown in the Declarations written notice of the nonrenewal less than 45 days before the expiration date.

If notice is mailed, proof of mailing will be sufficient proof of notice.

### C. Changes

This policy contains all the agreements between you and us concerning the insurance afforded. The first Named Insured shown in the Declarations is authorized to make changes in the terms of this policy with our consent. This policy's terms can be amended or waived only by endorsement issued by us and made a part of this policy.

### D. Concealment, Misrepresentation or Fraud

This policy is void in any case of fraud by you as it relates to this policy at any time. It is also void if you or any other insured, at any time, intentionally conceal or misrepresent a material fact concerning:

1. This policy;
2. The Covered Property;
3. Your interest in the Covered Property; or
4. A claim under this policy.

### E. Examination Of Your Books And Records

We may examine and audit your books and records as they relate to this policy at any time during the policy period and up to three years afterward.

### F. Inspections And Surveys

1. We have the right to but are not obligated to:
  - a. Make inspections and surveys at any time;
  - b. Give you reports on the conditions we find; and
  - c. Recommend changes.
2. Any inspections, surveys, reports or recommendations relate only to insurability and the premiums to be charged. We do not make safety inspections. We do not undertake to perform the duty of any person or organization to provide for the health or safety of workers or the public. And we do not warrant that conditions:
  - a. Are safe or healthful; or
  - b. Comply with laws, regulations, codes or standards.
3. This condition applies not only to us, but also to any rating, advisory, rate service or similar organization which makes insurance inspections, surveys, reports or recommendations.

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Page 1 of 2

**G. Liberalization**

If we adopt any revision that would broaden the coverage under this policy without additional premium within 45 days prior to or during the policy period, the broadening coverage will immediately apply to this policy.

**H. Premiums**

1. All Named Insureds shown in the Declarations are jointly and severally liable and responsible for the payment of all premiums.
2. The first Named Insured shown in the Declarations will be the payee for any return premiums we pay.

**I. Premium Audit**

1. This policy is subject to audit if a premium designation as an advance premium is shown in the Declarations. We will compute the final premium due when we determine your actual exposures.
2. Premium shown in this policy as advance premium is a deposit premium only. At the close of each audit period we will compute the earned premium for that period. Audit premiums are due and payable on notice to the first Named Insured. If the sum of the advance and audit premiums paid for the policy period is greater than the earned premium, we will return the excess to the first Named Insured.
3. The first Named Insured must keep records of the information we need for premium computation, and send us copies at such times as we may request.

**J. Transfer Of Your Rights And Duties Under This Policy**

Your rights and duties under this policy may not be transferred without our written consent except in the case of death of an individual named insured.

If you die, your rights and duties will be transferred to your legal representative but only while acting within the scope of duties as your legal representative. Until your legal representative is appointed, anyone having proper temporary custody of your property will have your rights and duties but only with respect to that property.

**K. Unintentional Errors or Omissions**

Your failure to disclose all hazards existing as of the inception date of this policy shall not prejudice you with respect to the coverage afforded by this policy, provided such failure or omission is not intentional. However, this provision does not affect our right to collect additional premium or exercise our right of cancellation or nonrenewal.

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**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**AMENDMENT OF CONDITIONS – CANCELLATION  
NOTICE OF CANCELLATION TO OTHERS**

This endorsement modifies the following:  
COMMON POLICY CONDITIONS

- I. Paragraph **A. Cancellation**, subparagraph 2. is replaced by the following:
  2. We may cancel this policy by mailing or delivering to the first Named Insured written notice of cancellation at least:
    - a. 30 days before the effective date of cancellation if we cancel for nonpayment of premium; or
    - b. 10 days before the effective date of cancellation if we cancel for any other reason.

II. Notice of Cancellation will also be sent to:

WELLS FARGO BANK  
2450 COLORADO AVE, SUITE 3000 WEST  
SANTA MONICA, CA 90404

CANTOR FITZGERALD SECURITIES  
110 EAST 59TH STREET  
NEW YORK, NY 10022



IL 01 41 09 08

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

## **NEW JERSEY CHANGES – CIVIL UNION**

This endorsement modifies insurance provided under the following:

COMMERCIAL AUTOMOBILE COVERAGE PART  
COMMERCIAL GENERAL LIABILITY COVERAGE PART  
COMMERCIAL LIABILITY UMBRELLA COVERAGE PART  
ELECTRONIC DATA LIABILITY COVERAGE PART  
EMPLOYMENT-RELATED PRACTICES LIABILITY COVERAGE PART  
FARM COVERAGE PART  
FARM UMBRELLA LIABILITY POLICY  
LIQUOR LIABILITY COVERAGE PART  
MEDICAL PROFESSIONAL LIABILITY COVERAGE PART  
OWNERS AND CONTRACTORS PROTECTIVE LIABILITY COVERAGE PART  
POLLUTION LIABILITY COVERAGE PART  
PRODUCT WITHDRAWAL COVERAGE PART  
PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE PART  
UNDERGROUND STORAGE TANK POLICY

**A. The term "spouse" is replaced by the following:**

Spouse or party to a civil union recognized under New Jersey law.

**B. Under the Commercial Auto Coverage Part, the term "family member" is replaced by the following:**

"Family member" means a person related to the:

1. Individual Named Insured by blood, adoption, marriage or civil union recognized under New Jersey law, who is a resident of such Named Insured's household, including a ward or foster child; or
2. Individual named in the Schedule by blood, adoption, marriage or civil union recognized under New Jersey law, who is a resident of the individual's household, including a ward or foster child, if the Drive Other Car Coverage – Broadened Coverage For Named Individual Endorsement is attached.

**C. With respect to coverage for the ownership, maintenance, or use of "covered autos" provided under the Commercial Liability Umbrella Coverage Part, the term "family member" is replaced by the following:**

"Family member" means a person related to you by blood, adoption, marriage or civil union recognized under New Jersey law, who is a resident of your household, including a ward or foster child.

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**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

## **NEW JERSEY CHANGES – CANCELLATION AND NONRENEWAL**

This endorsement modifies insurance provided under the following:

CAPITAL ASSETS PROGRAM (OUTPUT POLICY) COVERAGE PART  
COMMERCIAL AUTOMOBILE COVERAGE PART  
COMMERCIAL GENERAL LIABILITY COVERAGE PART  
COMMERCIAL INLAND MARINE COVERAGE PART  
COMMERCIAL LIABILITY UMBRELLA COVERAGE PART  
COMMERCIAL PROPERTY COVERAGE PART  
CRIME AND FIDELITY COVERAGE PART  
EMPLOYMENT-RELATED PRACTICES LIABILITY COVERAGE PART  
EQUIPMENT BREAKDOWN COVERAGE PART  
FARM COVERAGE PART  
FARM UMBRELLA LIABILITY POLICY  
LIQUOR LIABILITY COVERAGE PART  
POLLUTION LIABILITY COVERAGE PART  
PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE PART

- A.** Pursuant to New Jersey law, this policy cannot be cancelled or nonrenewed for any underwriting reason or guideline which is arbitrary, capricious or unfairly discriminatory or without adequate prior notice to the insured. The underwriting reasons or guidelines that an insurer can use to cancel or nonrenew this policy are maintained by the insurer in writing and will be furnished to the insured and/or the insured's lawful representative upon written request.

This provision shall not apply to any policy which has been in effect for less than 60 days at the time notice of cancellation is mailed or delivered, unless the policy is a renewal policy.

- B.** Paragraph 2. of the **Cancellation** Common Policy Condition is replaced by the following:

- 2.** If this policy has been in effect for less than 60 days, we may cancel this policy for any reason subject to the following:

- a.** We may cancel this policy by mailing or delivering to the first Named Insured and any person entitled to notice under this policy written notice, of cancellation, at least:

- (1)** 10 days before the effective date of cancellation if we cancel for:

- (a)** Nonpayment of premium; or

- (b)** Existence of a moral hazard, as defined in N.J.A.C. 11:1-20.2(f) as follows:

- (i)** "The risk, danger or probability that the insured will destroy, or permit to be destroyed, the insured property for the purpose of collecting the insurance proceeds. Any change in the circumstances of an insured that will increase the probability of such a destruction may be considered a 'moral hazard'; and
- (ii)** "The substantial risk, danger or probability that the character, circumstances or personal habits of the insured may increase the possibility of loss or liability for which an insurer will be held responsible. Any change in the character or circumstances of an individual, corporate, partnership or other insured that will increase the probability of such a loss or liability may be considered a 'moral hazard'".

- (2) 30 days before the effective date of cancellation if we cancel for any other reason.
- b. In the notice of cancellation which is sent to the first Named Insured, we will state the reason for cancellation.
- C. The following is added to the **Cancellation Common Policy Condition**:
- 7. Cancellation Of Policies In Effect For 60 Days Or More**
- a. If this policy has been in effect for 60 days or more, or is a renewal of a policy we issued, we may cancel this policy only for one or more of the following reasons:
- (1) Nonpayment of premium;
  - (2) Existence of a moral hazard, as defined in N.J.A.C. 11:1-20.2(f);
  - (3) Material misrepresentation or nondisclosure to us of a material fact at the time of acceptance of the risk;
  - (4) Increased hazard or material change in the risk assumed which we could not have reasonably contemplated at the time of assumption of the risk;
  - (5) Substantial breaches of contractual duties, conditions or warranties that materially affect the nature and/or insurability of the risk;
  - (6) Lack of cooperation from the insured on loss control matters materially affecting insurability of the risk;
  - (7) Fraudulent acts against us by the insured or its representative that materially affect the nature of the risk insured;
  - (8) Loss of or reduction in available insurance capacity;
  - (9) Material increase in exposure arising out of changes in statutory or case law subsequent to the issuance of the insurance contract or any subsequent renewal;
  - (10) Loss of or substantial changes in applicable reinsurance;
  - (11) Failure by the insured to comply with any Federal, State or local fire, health, safety or building or construction regulation, law or ordinance with respect to an insured risk which substantially increases any hazard insured against within 60 days of written notification of a violation of any such law, regulation or ordinance;
- (12) Failure by the insured to provide reasonable and necessary underwriting information to us upon written request therefore and a reasonable opportunity to respond.
- (13) Agency termination, provided:
- (a) We document that replacement coverage at comparable rates and terms has been provided to the first Named Insured, and we have informed the first Named Insured, in writing, of the right to continue coverage with us; or
  - (b) We have informed the first Named Insured, in writing, of the right to continue coverage with us and the first Named Insured has agreed, in writing, to the cancellation or nonrenewal based on the termination of the first Named Insured's appointed agent.
- (14) Any other reasons in accordance with our underwriting guidelines for cancellation of commercial lines coverage.
- b. If we cancel this policy based on Paragraph 7.a.(1) or (2) above, we will mail or deliver a written notice, to the first Named Insured and any person entitled to notice under this policy, at least 10 days before the effective date of cancellation. If we cancel this policy for any other reason listed above, we will mail or deliver a written notice to the first Named Insured and any person entitled to notice under this policy, not more than 120 days nor less than 30 days before the effective date of such cancellation.
- c. In the notice of cancellation which is sent to the first Named Insured, we will state the reason for cancellation. For cancellation due to the nonpayment of premium, the notice will state the effect of nonpayment by the due date. Cancellation for nonpayment of premium will not be effective if payment of the amount due is made before the effective date set forth in the notice.
- d. Notice will be sent to the last mailing addresses known to us, by:
- (1) Certified mail; or
  - (2) First class mail, if we have obtained from the post office a date stamped proof of mailing showing names and addresses.

- e. We need not send notice of cancellation if you have:
  - (1) Replaced coverage elsewhere; or
  - (2) Specifically requested termination.
- D. The following is added and supersedes any other provision to the contrary:

**NONRENEWAL**

- 1. We may elect not to renew this policy for any reason permitted to cancel it. If we elect not to renew this policy, we will mail a notice of nonrenewal, stating the reasons for nonrenewal, to the first Named Insured at least 30 days but not more than 120 days before the expiration date of this policy. If this policy does not have a fixed expiration date, it shall be deemed to expire annually on the anniversary of its inception.

- 2. This notice will be sent to the first Named Insured at the last mailing address known to us by:
  - a. Certified mail; or
  - b. First class mail, if we have obtained from the post office a date stamped proof of mailing showing the first Named Insured's name and address.
- 3. We need not mail or deliver this notice if you have:
  - a. Replaced coverage elsewhere; or
  - b. Specifically requested termination.



**COMMERCIAL GENERAL LIABILITY COVERAGE PART  
SUPPLEMENTAL DECLARATIONS**

**NAVIGATORS INSURANCE COMPANY**

**Policy Number**  
**CH17NCP020480-00**

Named Insured **PERNIX THERAPEUTICS HOLDINGS**

Effective Date: **11-30-2017**  
**12:01 A.M., Standard Time**

Agent Name **CONNER STRONG COMPANIES**

Agent No. **CONN0358**

**Item 1. Business Description:**

**Item 2. Limits of Insurance**

| Coverage   | Limit of Liability  |   |
|--|---------------------|---|
| Aggregate Limits of Liability                            | <b>NOT COVERED</b>  | Products/Completed Operations Aggregate   |
|  | <b>\$ 2,000,000</b> | General Aggregate (other than Products/Completed Operations)  |
| Coverage A - Bodily Injury and Property Damage Liability | <b>\$ 1,000,000</b> | any one occurrence subject to the Products/Completed Operations and General Aggregate Limits of Liability |
| Damage To Premises Rented To You                         | <b>\$ 1,000,000</b> | any one premises subject to the Coverage A occurrence and the General Aggregate Limits of Liability       |
| Coverage B - Personal and Advertising Injury Liability   | <b>\$ 1,000,000</b> | any one person or organization subject to the General Aggregate Limits of Liability                       |
| Coverage C - Medical Payments                            | <b>10,000</b>       | any one person subject to the Coverage A occurrence and the General Aggregate Limits of Liability         |

**Item 3. Retroactive Date**

This Insurance does not apply to "bodily injury", "property damage" or "personal and advertising injury" which occurs before the Retroactive Date, if any, shown here: \_\_\_\_\_

(Enter Date or "None" if no Retroactive Date applies)

**Item 4. Form of Business and Location of Premises**

Forms of Business: **CORPORATION**

Location of All Premises You Own, Rent or Occupy:

**See Schedule of Locations**

**Item 5. Forms and Endorsements**

Form(s) and Endorsement(s) made a part of this policy at time of issue:

**See Schedule of Forms and Endorsements**

**Item 6. Premiums**

Coverage Part Premium: **\$ 33,483.00**

Other Premium:

Total Premium: **\$ 33,483.00**

THESE DECLARATIONS ARE PART OF THE POLICY DECLARATIONS CONTAINING THE NAME OF THE INSURED AND THE POLICY PERIOD.  
**GL-DEC (12/01)**



**COMMERCIAL GENERAL  
LIABILITY COVERAGE SCHEDULE  
NAVIGATORS INSURANCE COMPANY**

**Policy Number  
CH17NCP020480-00**

Named Insured **PERNIX THERAPEUTICS HOLDINGS**

Effective Date: **11-30-17**  
12:01 A.M., Standard Time

Agent Name **CONNER STRONG COMPANIES**

Agent No. **CONN0358**

**Item 1. Location of Premises**

Location of All Premises You Own, Rent or Occupy:  
**See Schedule of Locations**

|   |   |                               |
|---|---|-------------------------------|
| Code No.<br>52343   | Premium Basis<br>GROSS SALES/NEAREST THOUSAND | Premises/Operations           |
| Location<br>001/001   | Exposure<br>\$103,346,525                     | Covered                       |
| Classification:<br>DRUG, MEDICINE OR PHARMACEUTICAL<br>PREPARATIONS MFG. - OTHER THAN FOR<br>ANIMAL USE |   | Products/Completed Operations |
|   |   | Excluded                      |
|   |   |                               |
| Code No.  | Premium Basis                                 | Premises/Operations           |
| Location  | Exposure                                      | Covered                       |
| Classification:<br>TERRORISM  |   | Products/Completed Operations |
|   |   | Included                      |
|   |   |                               |
| Code No.<br>92100   | Premium Basis                                 | Premises/Operations           |
| Location  | Exposure<br>175                               | Covered                       |
| Classification:<br>EMPLOYEE BENEFITS LIABILITY  |   | Products/Completed Operations |
|   |   | Included                      |
|   |   |                               |
| Code No.<br>44444   | Premium Basis                                 | Premises/Operations           |
| Location  | Exposure                                      | Covered                       |
| Classification:<br>POLARIS ENDORSEMENTS   |   | Products/Completed Operations |
|   |   | Included                      |
|   |   |                               |

**COMMERCIAL GENERAL LIABILITY**  
**CG 00 01 04 13**

## COMMERCIAL GENERAL LIABILITY COVERAGE FORM

Various provisions in this policy restrict coverage. Read the entire policy carefully to determine rights, duties and what is and is not covered.

Throughout this policy the words "you" and "your" refer to the Named Insured shown in the Declarations, and any other person or organization qualifying as a Named Insured under this policy. The words "we", "us" and "our" refer to the company providing this insurance.

The word "insured" means any person or organization qualifying as such under Section II – Who Is An Insured.

Other words and phrases that appear in quotation marks have special meaning. Refer to Section V – Definitions.

### SECTION I – COVERAGES

#### COVERAGE A – BODILY INJURY AND PROPERTY DAMAGE LIABILITY

##### 1. Insuring Agreement

- a. We will pay those sums that the insured becomes legally obligated to pay as damages because of "bodily injury" or "property damage" to which this insurance applies. We will have the right and duty to defend the insured against any "suit" seeking those damages. However, we will have no duty to defend the insured against any "suit" seeking damages for "bodily injury" or "property damage" to which this insurance does not apply. We may, at our discretion, investigate any "occurrence" and settle any claim or "suit" that may result. But:

- (1) The amount we will pay for damages is limited as described in Section III – Limits Of Insurance; and
- (2) Our right and duty to defend ends when we have used up the applicable limit of insurance in the payment of judgments or settlements under Coverages A or B or medical expenses under Coverage C.

No other obligation or liability to pay sums or perform acts or services is covered unless explicitly provided for under Supplementary Payments – Coverages A and B.

- b. This insurance applies to "bodily injury" and "property damage" only if:

- (1) The "bodily injury" or "property damage" is caused by an "occurrence" that takes place in the "coverage territory";

- (2) The "bodily injury" or "property damage" occurs during the policy period; and
  - (3) Prior to the policy period, no insured listed under Paragraph 1. of Section II – Who Is An Insured and no "employee" authorized by you to give or receive notice of an "occurrence" or claim, knew that the "bodily injury" or "property damage" had occurred, in whole or in part. If such a listed insured or authorized "employee" knew, prior to the policy period, that the "bodily injury" or "property damage" occurred, then any continuation, change or resumption of such "bodily injury" or "property damage" during or after the policy period will be deemed to have been known prior to the policy period.
- c. "Bodily injury" or "property damage" which occurs during the policy period and was not, prior to the policy period, known to have occurred by any insured listed under Paragraph 1. of Section II – Who Is An Insured or any "employee" authorized by you to give or receive notice of an "occurrence" or claim, includes any continuation, change or resumption of that "bodily injury" or "property damage" after the end of the policy period.
- d. "Bodily injury" or "property damage" will be deemed to have been known to have occurred at the earliest time when any insured listed under Paragraph 1. of Section II – Who Is An Insured or any "employee" authorized by you to give or receive notice of an "occurrence" or claim:
- (1) Reports all, or any part, of the "bodily injury" or "property damage" to us or any other insurer;
  - (2) Receives a written or verbal demand or claim for damages because of the "bodily injury" or "property damage"; or
  - (3) Becomes aware by any other means that "bodily injury" or "property damage" has occurred or has begun to occur.
- e. Damages because of "bodily injury" include damages claimed by any person or organization for care, loss of services or death resulting at any time from the "bodily injury".



**2. Exclusions**

This insurance does not apply to:

**a. Expected Or Intended Injury**

"Bodily injury" or "property damage" expected or intended from the standpoint of the insured. This exclusion does not apply to "bodily injury" resulting from the use of reasonable force to protect persons or property.

**b. Contractual Liability**

"Bodily injury" or "property damage" for which the insured is obligated to pay damages by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for damages:

- (1) That the insured would have in the absence of the contract or agreement; or
- (2) Assumed in a contract or agreement that is an "insured contract", provided the "bodily injury" or "property damage" occurs subsequent to the execution of the contract or agreement. Solely for the purposes of liability assumed in an "insured contract", reasonable attorneys' fees and necessary litigation expenses incurred by or for a party other than an insured are deemed to be damages because of "bodily injury" or "property damage", provided:
  - (a) Liability to such party for, or for the cost of, that party's defense has also been assumed in the same "insured contract"; and
  - (b) Such attorneys' fees and litigation expenses are for defense of that party against a civil or alternative dispute resolution proceeding in which damages to which this insurance applies are alleged.

**c. Liquor Liability**

"Bodily injury" or "property damage" for which any insured may be held liable by reason of:

- (1) Causing or contributing to the intoxication of any person;
- (2) The furnishing of alcoholic beverages to a person under the legal drinking age or under the influence of alcohol; or
- (3) Any statute, ordinance or regulation relating to the sale, gift, distribution or use of alcoholic beverages.

This exclusion applies even if the claims against any insured allege negligence or other wrongdoing in:

- (a) The supervision, hiring, employment, training or monitoring of others by that insured; or
- (b) Providing or failing to provide transportation with respect to any person that may be under the influence of alcohol;

if the "occurrence" which caused the "bodily injury" or "property damage", involved that which is described in Paragraph (1), (2) or (3) above.

However, this exclusion applies only if you are in the business of manufacturing, distributing, selling, serving or furnishing alcoholic beverages. For the purposes of this exclusion, permitting a person to bring alcoholic beverages on your premises, for consumption on your premises, whether or not a fee is charged or a license is required for such activity, is not by itself considered the business of selling, serving or furnishing alcoholic beverages.

**d. Workers' Compensation And Similar Laws**

Any obligation of the insured under a workers' compensation, disability benefits or unemployment compensation law or any similar law.

**e. Employer's Liability**

"Bodily injury" to:

- (1) An "employee" of the insured arising out of and in the course of:
  - (a) Employment by the insured; or
  - (b) Performing duties related to the conduct of the insured's business; or
- (2) The spouse, child, parent, brother or sister of that "employee" as a consequence of Paragraph (1) above.

This exclusion applies whether the insured may be liable as an employer or in any other capacity and to any obligation to share damages with or repay someone else who must pay damages because of the injury.

This exclusion does not apply to liability assumed by the insured under an "insured contract".



**f. Pollution**

- (1) "Bodily injury" or "property damage" arising out of the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of "pollutants":
- (a) At or from any premises, site or location which is or was at any time owned or occupied by, or rented or loaned to, any insured. However, this subparagraph does not apply to:
    - (i) "Bodily injury" if sustained within a building and caused by smoke, fumes, vapor or soot produced by or originating from equipment that is used to heat, cool or dehumidify the building, or equipment that is used to heat water for personal use, by the building's occupants or their guests;
    - (ii) "Bodily injury" or "property damage" for which you may be held liable, if you are a contractor and the owner or lessee of such premises, site or location has been added to your policy as an additional insured with respect to your ongoing operations performed for that additional insured at that premises, site or location and such premises, site or location is not and never was owned or occupied by, or rented or loaned to, any insured, other than that additional insured; or
    - (iii) "Bodily injury" or "property damage" arising out of heat, smoke or fumes from a "hostile fire";
  - (b) At or from any premises, site or location which is or was at any time used by or for any insured or others for the handling, storage, disposal, processing or treatment of waste;
  - (c) Which are or were at any time transported, handled, stored, treated, disposed of, or processed as waste by or for:
    - (i) Any insured; or
    - (ii) Any person or organization for whom you may be legally responsible; or
  - (d) At or from any premises, site or location on which any insured or any contractors or subcontractors working directly or indirectly on any insured's behalf are performing operations if the "pollutants" are brought on or to the premises, site or location in connection with such operations by such insured, contractor or subcontractor. However, this subparagraph does not apply to:
    - (i) "Bodily injury" or "property damage" arising out of the escape of fuels, lubricants or other operating fluids which are needed to perform the normal electrical, hydraulic or mechanical functions necessary for the operation of "mobile equipment" or its parts, if such fuels, lubricants or other operating fluids escape from a vehicle part designed to hold, store or receive them. This exception does not apply if the "bodily injury" or "property damage" arises out of the intentional discharge, dispersal or release of the fuels, lubricants or other operating fluids, or if such fuels, lubricants or other operating fluids are brought on or to the premises, site or location with the intent that they be discharged, dispersed or released as part of the operations being performed by such insured, contractor or subcontractor;
    - (ii) "Bodily injury" or "property damage" sustained within a building and caused by the release of gases, fumes or vapors from materials brought into that building in connection with operations being performed by you or on your behalf by a contractor or subcontractor; or
    - (iii) "Bodily injury" or "property damage" arising out of heat, smoke or fumes from a "hostile fire".
  - (e) At or from any premises, site or location on which any insured or any contractors or subcontractors working directly or indirectly on any insured's behalf are performing operations if the operations are to test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of, "pollutants".

(2) Any loss, cost or expense arising out of any:

- (a) Request, demand, order or statutory or regulatory requirement that any insured or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of, "pollutants"; or
- (b) Claim or suit by or on behalf of a governmental authority for damages because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of, "pollutants".

However, this paragraph does not apply to liability for damages because of "property damage" that the insured would have in the absence of such request, demand, order or statutory or regulatory requirement, or such claim or "suit" by or on behalf of a governmental authority.

**g. Aircraft, Auto Or Watercraft**

"Bodily injury" or "property damage" arising out of the ownership, maintenance, use or entrustment to others of any aircraft, "auto" or watercraft owned or operated by or rented or loaned to any insured. Use includes operation and "loading or unloading".

This exclusion applies even if the claims against any insured allege negligence or other wrongdoing in the supervision, hiring, employment, training or monitoring of others by that insured, if the "occurrence" which caused the "bodily injury" or "property damage" involved the ownership, maintenance, use or entrustment to others of any aircraft, "auto" or watercraft that is owned or operated by or rented or loaned to any insured.

This exclusion does not apply to:

- (1) A watercraft while ashore on premises you own or rent;
- (2) A watercraft you do not own that is:
  - (a) Less than 26 feet long; and
  - (b) Not being used to carry persons or property for a charge;
- (3) Parking an "auto" on, or on the ways next to, premises you own or rent, provided the "auto" is not owned by or rented or loaned to you or the insured;
- (4) Liability assumed under any "insured contract" for the ownership, maintenance or use of aircraft or watercraft; or

(5) "Bodily injury" or "property damage" arising out of:

- (a) The operation of machinery or equipment that is attached to, or part of, a land vehicle that would qualify under the definition of "mobile equipment" if it were not subject to a compulsory or financial responsibility law or other motor vehicle insurance law where it is licensed or principally garaged; or
- (b) The operation of any of the machinery or equipment listed in Paragraph f.(2) or f.(3) of the definition of "mobile equipment".

**h. Mobile Equipment**

"Bodily injury" or "property damage" arising out of:

- (1) The transportation of "mobile equipment" by an "auto" owned or operated by or rented or loaned to any insured; or
- (2) The use of "mobile equipment" in, or while in practice for, or while being prepared for, any prearranged racing, speed, demolition, or stunting activity.

**i. War**

"Bodily injury" or "property damage", however caused, arising, directly or indirectly, out of:

- (1) War, including undeclared or civil war;
- (2) Warlike action by a military force, including action in hindering or defending against an actual or expected attack, by any government, sovereign or other authority using military personnel or other agents; or
- (3) Insurrection, rebellion, revolution, usurped power, or action taken by governmental authority in hindering or defending against any of these.

**j. Damage To Property**

"Property damage" to:

- (1) Property you own, rent, or occupy, including any costs or expenses incurred by you, or any other person, organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property;
- (2) Premises you sell, give away or abandon, if the "property damage" arises out of any part of those premises;
- (3) Property loaned to you;

- (4) Personal property in the care, custody or control of the insured;
- (5) That particular part of real property on which you or any contractors or subcontractors working directly or indirectly on your behalf are performing operations; if the "property damage" arises out of those operations; or
- (6) That particular part of any property that must be restored, repaired or replaced because "your work" was incorrectly performed on it.

Paragraphs (1), (3) and (4) of this exclusion do not apply to "property damage" (other than damage by fire) to premises, including the contents of such premises, rented to you for a period of seven or fewer consecutive days. A separate limit of insurance applies to Damage To Premises Rented To You as described in Section III – Limits Of Insurance.

Paragraph (2) of this exclusion does not apply if the premises are "your work" and were never occupied, rented or held for rental by you.

Paragraphs (3), (4), (5) and (6) of this exclusion do not apply to liability assumed under a sidetrack agreement.

Paragraph (6) of this exclusion does not apply to "property damage" included in the "products-completed operations hazard".

**k. Damage To Your Product**

"Property damage" to "your product" arising out of it or any part of it.

**l. Damage To Your Work**

"Property damage" to "your work" arising out of it or any part of it and included in the "products-completed operations hazard".

This exclusion does not apply if the damaged work or the work out of which the damage arises was performed on your behalf by a subcontractor.

**m. Damage To Impaired Property Or Property Not Physically Injured**

"Property damage" to "impaired property" or property that has not been physically injured, arising out of:

- (1) A defect, deficiency, inadequacy or dangerous condition in "your product" or "your work"; or
- (2) A delay or failure by you or anyone acting on your behalf to perform a contract or agreement in accordance with its terms.

This exclusion does not apply to the loss of use of other property arising out of sudden and accidental physical injury to "your product" or "your work" after it has been put to its intended use.

**n. Recall Of Products, Work Or Impaired Property**

Damages claimed for any loss, cost or expense incurred by you or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

- (1) "Your product";
- (2) "Your work"; or
- (3) "Impaired property";

if such product, work, or property is withdrawn or recalled from the market or from use by any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition in it.

**o. Personal And Advertising Injury**

"Bodily injury" arising out of "personal and advertising injury".

**p. Electronic Data**

Damages arising out of the loss of, loss of use of, damage to, corruption of, inability to access, or inability to manipulate electronic data.

However, this exclusion does not apply to liability for damages because of "bodily injury".

As used in this exclusion, electronic data means information, facts or programs stored as or on, created or used on, or transmitted to or from computer software, including systems and applications software, hard or floppy disks, CD-ROMs, tapes, drives, cells, data processing devices or any other media which are used with electronically controlled equipment.

**q. Recording And Distribution Of Material Or Information In Violation Of Law**

"Bodily injury" or "property damage" arising directly or indirectly out of any action or omission that violates or is alleged to violate:

- (1) The Telephone Consumer Protection Act (TCPA), including any amendment of or addition to such law;
- (2) The CAN-SPAM Act of 2003, including any amendment of or addition to such law;
- (3) The Fair Credit Reporting Act (FCRA), and any amendment of or addition to such law, including the Fair and Accurate Credit Transactions Act (FACTA); or

- (4) Any federal, state or local statute, ordinance or regulation, other than the TCPA, CAN-SPAM Act of 2003 or FCRA and their amendments and additions, that addresses, prohibits, or limits the printing, dissemination, disposal, collecting, recording, sending, transmitting, communicating or distribution of material or information.

Exclusions c. through n. do not apply to damage by fire to premises while rented to you or temporarily occupied by you with permission of the owner. A separate limit of insurance applies to this coverage as described in Section III – Limits Of Insurance.

## **COVERAGE B – PERSONAL AND ADVERTISING INJURY LIABILITY**

### **1. Insuring Agreement**

- a. We will pay those sums that the insured becomes legally obligated to pay as damages because of "personal and advertising injury" to which this insurance applies. We will have the right and duty to defend the insured against any "suit" seeking those damages. However, we will have no duty to defend the insured against any "suit" seeking damages for "personal and advertising injury" to which this insurance does not apply. We may, at our discretion, investigate any offense and settle any claim or "suit" that may result. But:
- (1) The amount we will pay for damages is limited as described in Section III – Limits Of Insurance; and
  - (2) Our right and duty to defend end when we have used up the applicable limit of insurance in the payment of judgments or settlements under Coverages A or B or medical expenses under Coverage C.
- No other obligation or liability to pay sums or perform acts or services is covered unless explicitly provided for under Supplementary Payments – Coverages A and B.
- b. This insurance applies to "personal and advertising injury" caused by an offense arising out of your business but only if the offense was committed in the "coverage territory" during the policy period.

### **2. Exclusions**

This insurance does not apply to:

#### **a. Knowing Violation Of Rights Of Another**

"Personal and advertising injury" caused by or at the direction of the insured with the knowledge that the act would violate the rights of another and would inflict "personal and advertising injury".

#### **b. Material Published With Knowledge Of Falsity**

"Personal and advertising injury" arising out of oral or written publication, in any manner, of material, if done by or at the direction of the insured with knowledge of its falsity.

#### **c. Material Published Prior To Policy Period**

"Personal and advertising injury" arising out of oral or written publication, in any manner, of material whose first publication took place before the beginning of the policy period.

#### **d. Criminal Acts**

"Personal and advertising injury" arising out of a criminal act committed by or at the direction of the insured.

#### **e. Contractual Liability**

"Personal and advertising injury" for which the insured has assumed liability in a contract or agreement. This exclusion does not apply to liability for damages that the insured would have in the absence of the contract or agreement.

#### **f. Breach Of Contract**

"Personal and advertising injury" arising out of a breach of contract, except an implied contract to use another's advertising idea in your "advertisement".

#### **g. Quality Or Performance Of Goods – Failure To Conform To Statements**

"Personal and advertising injury" arising out of the failure of goods, products or services to conform with any statement of quality or performance made in your "advertisement".

#### **h. Wrong Description Of Prices**

"Personal and advertising injury" arising out of the wrong description of the price of goods, products or services stated in your "advertisement".

**i. Infringement Of Copyright, Patent, Trademark Or Trade Secret**

"Personal and advertising injury" arising out of the infringement of copyright, patent, trademark, trade secret or other intellectual property rights. Under this exclusion, such other intellectual property rights do not include the use of another's advertising idea in your "advertisement".

However, this exclusion does not apply to infringement, in your "advertisement", of copyright, trade dress or slogan.

**j. Insureds In Media And Internet Type Businesses**

"Personal and advertising injury" committed by an insured whose business is:

- (1) Advertising, broadcasting, publishing or telecasting;
- (2) Designing or determining content of web sites for others; or
- (3) An Internet search, access, content or service provider.

However, this exclusion does not apply to Paragraphs 14.a., b. and c. of "personal and advertising injury" under the Definitions section.

For the purposes of this exclusion, the placing of frames, borders or links, or advertising, for you or others anywhere on the Internet, is not by itself, considered the business of advertising, broadcasting, publishing or telecasting.

**k. Electronic Chatrooms Or Bulletin Boards**

"Personal and advertising injury" arising out of an electronic chatroom or bulletin board the insured hosts, owns, or over which the insured exercises control.

**l. Unauthorized Use Of Another's Name Or Product**

"Personal and advertising injury" arising out of the unauthorized use of another's name or product in your e-mail address, domain name or metatag, or any other similar tactics to mislead another's potential customers.

**m. Pollution**

"Personal and advertising injury" arising out of the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of "pollutants" at any time.

**n. Pollution-related**

Any loss, cost or expense arising out of any:

- (1) Request, demand, order or statutory or regulatory requirement that any insured or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of, "pollutants"; or
- (2) Claim or suit by or on behalf of a governmental authority for damages because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of, "pollutants".

**o. War**

"Personal and advertising injury", however caused, arising, directly or indirectly, out of:

- (1) War, including undeclared or civil war;
- (2) Warlike action by a military force, including action in hindering or defending against an actual or expected attack, by any government, sovereign or other authority using military personnel or other agents; or
- (3) Insurrection, rebellion, revolution, usurped power, or action taken by governmental authority in hindering or defending against any of these.

**p. Recording And Distribution Of Material Or Information In Violation Of Law**

"Personal and advertising injury" arising directly or indirectly out of any action or omission that violates or is alleged to violate:

- (1) The Telephone Consumer Protection Act (TCPA), including any amendment of or addition to such law;
- (2) The CAN-SPAM Act of 2003, including any amendment of or addition to such law;
- (3) The Fair Credit Reporting Act (FCRA), and any amendment of or addition to such law, including the Fair and Accurate Credit Transactions Act (FACTA); or
- (4) Any federal, state or local statute, ordinance or regulation, other than the TCPA, CAN-SPAM Act of 2003 or FCRA and their amendments and additions, that addresses, prohibits, or limits the printing, dissemination, disposal, collecting, recording, sending, transmitting, communicating or distribution of material or information.



**COVERAGE C – MEDICAL PAYMENTS****1. Insuring Agreement**

a. We will pay medical expenses as described below for "bodily injury" caused by an accident:

- (1) On premises you own or rent;
- (2) On ways next to premises you own or rent; or
- (3) Because of your operations;

provided that:

- (a) The accident takes place in the "coverage territory" and during the policy period;
- (b) The expenses are incurred and reported to us within one year of the date of the accident; and
- (c) The injured person submits to examination, at our expense, by physicians of our choice as often as we reasonably require.

b. We will make these payments regardless of fault. These payments will not exceed the applicable limit of insurance. We will pay reasonable expenses for:

- (1) First aid administered at the time of an accident;
- (2) Necessary medical, surgical, X-ray and dental services, including prosthetic devices; and
- (3) Necessary ambulance, hospital, professional nursing and funeral services.

**2. Exclusions**

We will not pay expenses for "bodily injury":

**a. Any Insured**

To any insured, except "volunteer workers".

**b. Hired Person**

To a person hired to do work for or on behalf of any insured or a tenant of any insured.

**c. Injury On Normally Occupied Premises**

To a person injured on that part of premises you own or rent that the person normally occupies.

**d. Workers' Compensation And Similar Laws**

To a person, whether or not an "employee" of any insured, if benefits for the "bodily injury" are payable or must be provided under a workers' compensation or disability benefits law or a similar law.

**e. Athletics Activities**

To a person injured while practicing, instructing or participating in any physical exercises or games, sports, or athletic contests.

**f. Products-Completed Operations Hazard**

Included within the "products-completed operations hazard".

**g. Coverage A Exclusions**

Excluded under Coverage A.

**SUPPLEMENTARY PAYMENTS – COVERAGES A AND B**

1. We will pay, with respect to any claim we investigate or settle, or any "suit" against an insured we defend:

a. All expenses we incur.

b. Up to \$250 for cost of bail bonds required because of accidents or traffic law violations arising out of the use of any vehicle to which the Bodily Injury Liability Coverage applies. We do not have to furnish these bonds.

c. The cost of bonds to release attachments, but only for bond amounts within the applicable limit of insurance. We do not have to furnish these bonds.

d. All reasonable expenses incurred by the insured at our request to assist us in the investigation or defense of the claim or "suit", including actual loss of earnings up to \$250 a day because of time off from work.

e. All court costs taxed against the insured in the "suit". However, these payments do not include attorneys' fees or attorneys' expenses taxed against the insured.

f. Prejudgment interest awarded against the insured on that part of the judgment we pay. If we make an offer to pay the applicable limit of insurance, we will not pay any prejudgment interest based on that period of time after the offer.

- g. All interest on the full amount of any judgment that accrues after entry of the judgment and before we have paid, offered to pay, or deposited in court the part of the judgment that is within the applicable limit of insurance.

These payments will not reduce the limits of insurance.

2. If we defend an insured against a "suit" and an indemnitee of the insured is also named as a party to the "suit", we will defend that indemnitee if all of the following conditions are met:
- a. The "suit" against the indemnitee seeks damages for which the insured has assumed the liability of the indemnitee in a contract or agreement that is an "insured contract";
  - b. This insurance applies to such liability assumed by the insured;
  - c. The obligation to defend, or the cost of the defense of, that indemnitee, has also been assumed by the insured in the same "insured contract";
  - d. The allegations in the "suit" and the information we know about the "occurrence" are such that no conflict appears to exist between the interests of the insured and the interests of the indemnitee;
  - e. The indemnitee and the insured ask us to conduct and control the defense of that indemnitee against such "suit" and agree that we can assign the same counsel to defend the insured and the indemnitee; and
  - f. The indemnitee:
    - (1) Agrees in writing to:
      - (a) Cooperate with us in the investigation, settlement or defense of the "suit";
      - (b) Immediately send us copies of any demands, notices, summonses or legal papers received in connection with the "suit";
      - (c) Notify any other insurer whose coverage is available to the indemnitee; and
      - (d) Cooperate with us with respect to coordinating other applicable insurance available to the indemnitee; and
    - (2) Provides us with written authorization to:
      - (a) Obtain records and other information related to the "suit"; and
      - (b) Conduct and control the defense of the indemnitee in such "suit".

So long as the above conditions are met, attorneys' fees incurred by us in the defense of that indemnitee, necessary litigation expenses incurred by us and necessary litigation expenses incurred by the indemnitee at our request will be paid as Supplementary Payments. Notwithstanding the provisions of Paragraph 2.b.(2) of Section I — Coverage A — Bodily Injury And Property Damage Liability, such payments will not be deemed to be damages for "bodily injury" and "property damage" and will not reduce the limits of insurance.

Our obligation to defend an insured's indemnitee and to pay for attorneys' fees and necessary litigation expenses as Supplementary Payments ends when we have used up the applicable limit of insurance in the payment of judgments or settlements or the conditions set forth above, or the terms of the agreement described in Paragraph f. above, are no longer met.

## SECTION II — WHO IS AN INSURED

1. If you are designated in the Declarations as:
- a. An individual, you and your spouse are insureds, but only with respect to the conduct of a business of which you are the sole owner.
  - b. A partnership or joint venture, you are an insured. Your members, your partners, and their spouses are also insureds, but only with respect to the conduct of your business.
  - c. A limited liability company, you are an insured. Your members are also insureds, but only with respect to the conduct of your business. Your managers are insureds, but only with respect to their duties as your managers.
  - d. An organization other than a partnership, joint venture or limited liability company, you are an insured. Your "executive officers" and directors are insureds, but only with respect to their duties as your officers or directors. Your stockholders are also insureds, but only with respect to their liability as stockholders.
  - e. A trust, you are an insured. Your trustees are also insureds, but only with respect to their duties as trustees.

2. Each of the following is also an insured:

- a. Your "volunteer workers" only while performing duties related to the conduct of your business, or your "employees", other than either your "executive officers" (if you are an organization other than a partnership, joint venture or limited liability company) or your managers (if you are a limited liability company), but only for acts within the scope of their employment by you or while performing duties related to the conduct of your business. However, none of these "employees" or "volunteer workers" are insureds for:

(1) "Bodily injury" or "personal and advertising injury":

- (a) To you, to your partners or members (if you are a partnership or joint venture), to your members (if you are a limited liability company), to a co-"employee" while in the course of his or her employment or performing duties related to the conduct of your business, or to your other "volunteer workers" while performing duties related to the conduct of your business;
- (b) To the spouse, child, parent, brother or sister of that co-"employee" or "volunteer worker" as a consequence of Paragraph (1)(a) above;
- (c) For which there is any obligation to share damages with or repay someone else who must pay damages because of the injury described in Paragraph (1)(a) or (b) above; or
- (d) Arising out of his or her providing or failing to provide professional health care services.

(2) "Property damage" to property:

- (a) Owned, occupied or used by;
  - (b) Rented to, in the care, custody or control of, or over which physical control is being exercised for any purpose by;
- you, any of your "employees", "volunteer workers", any partner or member (if you are a partnership or joint venture), or any member (if you are a limited liability company).

- b. Any person (other than your "employee" or "volunteer worker"), or any organization while acting as your real estate manager.

- c. Any person or organization having proper temporary custody of your property if you die, but only:

- (1) With respect to liability arising out of the maintenance or use of that property; and
- (2) Until your legal representative has been appointed.

- d. Your legal representative if you die, but only with respect to duties as such. That representative will have all your rights and duties under this Coverage Part.

3. Any organization you newly acquire or form, other than a partnership, joint venture or limited liability company, and over which you maintain ownership or majority interest, will qualify as a Named Insured if there is no other similar insurance available to that organization. However:

- a. Coverage under this provision is afforded only until the 90th day after you acquire or form the organization or the end of the policy period, whichever is earlier;
- b. Coverage **A** does not apply to "bodily injury" or "property damage" that occurred before you acquired or formed the organization; and
- c. Coverage **B** does not apply to "personal and advertising injury" arising out of an offense committed before you acquired or formed the organization.

No person or organization is an insured with respect to the conduct of any current or past partnership, joint venture or limited liability company that is not shown as a Named Insured in the Declarations.

### SECTION III – LIMITS OF INSURANCE

1. The Limits of Insurance shown in the Declarations and the rules below fix the most we will pay regardless of the number of:

- a. Insureds;
- b. Claims made or "suits" brought; or
- c. Persons or organizations making claims or bringing "suits".

2. The General Aggregate Limit is the most we will pay for the sum of:

- a. Medical expenses under Coverage **C**;
- b. Damages under Coverage **A**, except damages because of "bodily injury" or "property damage" included in the "products-completed operations hazard"; and
- c. Damages under Coverage **B**.



3. The Products-Completed Operations Aggregate Limit is the most we will pay under Coverage **A** for damages because of "bodily injury" and "property damage" included in the "products-completed operations hazard".
4. Subject to Paragraph 2. above, the Personal And Advertising Injury Limit is the most we will pay under Coverage **B** for the sum of all damages because of all "personal and advertising injury" sustained by any one person or organization.
5. Subject to Paragraph 2. or 3. above, whichever applies, the Each Occurrence Limit is the most we will pay for the sum of:
  - a. Damages under Coverage **A**; and
  - b. Medical expenses under Coverage **C** because of all "bodily injury" and "property damage" arising out of any one "occurrence".
6. Subject to Paragraph 5. above, the Damage To Premises Rented To You Limit is the most we will pay under Coverage **A** for damages because of "property damage" to any one premises, while rented to you, or in the case of damage by fire, while rented to you or temporarily occupied by you with permission of the owner.
7. Subject to Paragraph 5. above, the Medical Expense Limit is the most we will pay under Coverage **C** for all medical expenses because of "bodily injury" sustained by any one person.
- (3) The nature and location of any injury or damage arising out of the "occurrence" or offense.
- b. If a claim is made or "suit" is brought against any insured, you must:
  - (1) Immediately record the specifics of the claim or "suit" and the date received; and
  - (2) Notify us as soon as practicable.

You must see to it that we receive written notice of the claim or "suit" as soon as practicable.
- c. You and any other involved insured must:
  - (1) Immediately send us copies of any demands, notices, summonses or legal papers received in connection with the claim or "suit";
  - (2) Authorize us to obtain records and other information;
  - (3) Cooperate with us in the investigation or settlement of the claim or defense against the "suit"; and
  - (4) Assist us, upon our request, in the enforcement of any right against any person or organization which may be liable to the insured because of injury or damage to which this insurance may also apply.
- d. No insured will, except at that insured's own cost, voluntarily make a payment, assume any obligation, or incur any expense, other than for first aid, without our consent.

The Limits of Insurance of this Coverage Part apply separately to each consecutive annual period and to any remaining period of less than 12 months, starting with the beginning of the policy period shown in the Declarations, unless the policy period is extended after issuance for an additional period of less than 12 months. In that case, the additional period will be deemed part of the last preceding period for purposes of determining the Limits of Insurance.

#### **SECTION IV – COMMERCIAL GENERAL LIABILITY CONDITIONS**

##### **1. Bankruptcy**

Bankruptcy or insolvency of the insured or of the insured's estate will not relieve us of our obligations under this Coverage Part.

##### **2. Duties In The Event Of Occurrence, Offense, Claim Or Suit**

- a. You must see to it that we are notified as soon as practicable of an "occurrence" or an offense which may result in a claim. To the extent possible, notice should include:
  - (1) How, when and where the "occurrence" or offense took place;
  - (2) The names and addresses of any injured persons and witnesses; and

##### **3. Legal Action Against Us**

No person or organization has a right under this Coverage Part:

- a. To join us as a party or otherwise bring us into a "suit" asking for damages from an insured; or
- b. To sue us on this Coverage Part unless all of its terms have been fully complied with.

A person or organization may sue us to recover on an agreed settlement or on a final judgment against an insured; but we will not be liable for damages that are not payable under the terms of this Coverage Part or that are in excess of the applicable limit of insurance. An agreed settlement means a settlement and release of liability signed by us, the insured and the claimant or the claimant's legal representative.

**4. Other Insurance**

If other valid and collectible insurance is available to the insured for a loss we cover under Coverages **A** or **B** of this Coverage Part, our obligations are limited as follows:

**a. Primary Insurance**

This insurance is primary except when Paragraph **b.** below applies. If this insurance is primary, our obligations are not affected unless any of the other insurance is also primary. Then, we will share with all that other insurance by the method described in Paragraph **c.** below.

**b. Excess Insurance**

(1) This insurance is excess over:

- (a) Any of the other insurance, whether primary, excess, contingent or on any other basis:
  - (i) That is Fire, Extended Coverage, Builder's Risk, Installation Risk or similar coverage for "your work";
  - (ii) That is Fire insurance for premises rented to you or temporarily occupied by you with permission of the owner;
  - (iii) That is insurance purchased by you to cover your liability as a tenant for "property damage" to premises rented to you or temporarily occupied by you with permission of the owner; or
  - (iv) If the loss arises out of the maintenance or use of aircraft, "autos" or watercraft to the extent not subject to Exclusion **g.** of Section **I** — Coverage **A** — Bodily Injury And Property Damage Liability.
- (b) Any other primary insurance available to you covering liability for damages arising out of the premises or operations, or the products and completed operations, for which you have been added as an additional insured.

(2) When this insurance is excess, we will have no duty under Coverages **A** or **B** to defend the insured against any "suit" if any other insurer has a duty to defend the insured against that "suit". If no other insurer defends, we will undertake to do so, but we will be entitled to the insured's rights against all those other insurers.

(3) When this insurance is excess over other insurance, we will pay only our share of the amount of the loss, if any, that exceeds the sum of:

- (a) The total amount that all such other insurance would pay for the loss in the absence of this insurance; and
- (b) The total of all deductible and self-insured amounts under all that other insurance.

(4) We will share the remaining loss, if any, with any other insurance that is not described in this Excess Insurance provision and was not bought specifically to apply in excess of the Limits of Insurance shown in the Declarations of this Coverage Part.

**c. Method Of Sharing**

If all of the other insurance permits contribution by equal shares, we will follow this method also. Under this approach each insurer contributes equal amounts until it has paid its applicable limit of insurance or none of the loss remains, whichever comes first.

If any of the other insurance does not permit contribution by equal shares, we will contribute by limits. Under this method, each insurer's share is based on the ratio of its applicable limit of insurance to the total applicable limits of insurance of all insurers.

**5. Premium Audit**

- a. We will compute all premiums for this Coverage Part in accordance with our rules and rates.
- b. Premium shown in this Coverage Part as advance premium is a deposit premium only. At the close of each audit period we will compute the earned premium for that period and send notice to the first Named Insured. The due date for audit and retrospective premiums is the date shown as the due date on the bill. If the sum of the advance and audit premiums paid for the policy period is greater than the earned premium, we will return the excess to the first Named Insured.
- c. The first Named Insured must keep records of the information we need for premium computation, and send us copies at such times as we may request.

**6. Representations**

By accepting this policy, you agree:

- a. The statements in the Declarations are accurate and complete;

- b. Those statements are based upon representations you made to us; and
- c. We have issued this policy in reliance upon your representations.

#### 7. Separation Of Insureds

Except with respect to the Limits of Insurance, and any rights or duties specifically assigned in this Coverage Part to the first Named Insured, this insurance applies:

- a. As if each Named Insured were the only Named Insured; and
- b. Separately to each insured against whom claim is made or "suit" is brought.

#### 8. Transfer Of Rights Of Recovery Against Others To Us

If the insured has rights to recover all or part of any payment we have made under this Coverage Part, those rights are transferred to us. The insured must do nothing after loss to impair them. At our request, the insured will bring "suit" or transfer those rights to us and help us enforce them.

#### 9. When We Do Not Renew

If we decide not to renew this Coverage Part, we will mail or deliver to the first Named Insured shown in the Declarations written notice of the nonrenewal not less than 30 days before the expiration date.

If notice is mailed, proof of mailing will be sufficient proof of notice.

### SECTION V – DEFINITIONS

1. "Advertisement" means a notice that is broadcast or published to the general public or specific market segments about your goods, products or services for the purpose of attracting customers or supporters. For the purposes of this definition:
  - a. Notices that are published include material placed on the Internet or on similar electronic means of communication; and
  - b. Regarding web sites, only that part of a web site that is about your goods, products or services for the purposes of attracting customers or supporters is considered an advertisement.
2. "Auto" means:
  - a. A land motor vehicle, trailer or semitrailer designed for travel on public roads, including any attached machinery or equipment; or
  - b. Any other land vehicle that is subject to a compulsory or financial responsibility law or other motor vehicle insurance law where it is licensed or principally garaged.

However, "auto" does not include "mobile equipment".

3. "Bodily injury" means bodily injury, sickness or disease sustained by a person, including death resulting from any of these at any time.

4. "Coverage territory" means:

- a. The United States of America (including its territories and possessions), Puerto Rico and Canada;
- b. International waters or airspace, but only if the injury or damage occurs in the course of travel or transportation between any places included in Paragraph a. above; or
- c. All other parts of the world if the injury or damage arises out of:
  - (1) Goods or products made or sold by you in the territory described in Paragraph a. above;
  - (2) The activities of a person whose home is in the territory described in Paragraph a. above, but is away for a short time on your business; or
  - (3) "Personal and advertising injury" offenses that take place through the Internet or similar electronic means of communication;

provided the insured's responsibility to pay damages is determined in a "suit" on the merits, in the territory described in Paragraph a. above or in a settlement we agree to.

5. "Employee" includes a "leased worker". "Employee" does not include a "temporary worker".
6. "Executive officer" means a person holding any of the officer positions created by your charter, constitution, bylaws or any other similar governing document.
7. "Hostile fire" means one which becomes uncontrollable or breaks out from where it was intended to be.
8. "Impaired property" means tangible property, other than "your product" or "your work", that cannot be used or is less useful because:
  - a. It incorporates "your product" or "your work" that is known or thought to be defective, deficient, inadequate or dangerous; or
  - b. You have failed to fulfill the terms of a contract or agreement;
 if such property can be restored to use by the repair, replacement, adjustment or removal of "your product" or "your work" or your fulfilling the terms of the contract or agreement.

9. "Insured contract" means:

- a. A contract for a lease of premises. However, that portion of the contract for a lease of premises that indemnifies any person or organization for damage by fire to premises while rented to you or temporarily occupied by you with permission of the owner is not an "insured contract";
- b. A sidetrack agreement;
- c. Any easement or license agreement, except in connection with construction or demolition operations on or within 50 feet of a railroad;
- d. An obligation, as required by ordinance, to indemnify a municipality, except in connection with work for a municipality;
- e. An elevator maintenance agreement;
- f. That part of any other contract or agreement pertaining to your business (including an indemnification of a municipality in connection with work performed for a municipality) under which you assume the tort liability of another party to pay for "bodily injury" or "property damage" to a third person or organization. Tort liability means a liability that would be imposed by law in the absence of any contract or agreement.

Paragraph f. does not include that part of any contract or agreement:

- (1) That indemnifies a railroad for "bodily injury" or "property damage" arising out of construction or demolition operations, within 50 feet of any railroad property and affecting any railroad bridge or trestle, tracks, roadbeds, tunnel, underpass or crossing;
- (2) That indemnifies an architect, engineer or surveyor for injury or damage arising out of:
  - (a) Preparing, approving, or failing to prepare or approve, maps, shop drawings, opinions, reports, surveys, field orders, change orders or drawings and specifications; or
  - (b) Giving directions or instructions, or failing to give them, if that is the primary cause of the injury or damage; or
- (3) Under which the insured, if an architect, engineer or surveyor, assumes liability for an injury or damage arising out of the insured's rendering or failure to render professional services, including those listed in (2) above and supervisory, inspection, architectural or engineering activities.

10. "Leased worker" means a person leased to you by a labor leasing firm under an agreement between you and the labor leasing firm, to perform duties related to the conduct of your business. "Leased worker" does not include a "temporary worker".

11. "Loading or unloading" means the handling of property:

- a. After it is moved from the place where it is accepted for movement into or onto an aircraft, watercraft or "auto";
- b. While it is in or on an aircraft, watercraft or "auto"; or
- c. While it is being moved from an aircraft, watercraft or "auto" to the place where it is finally delivered;

but "loading or unloading" does not include the movement of property by means of a mechanical device, other than a hand truck, that is not attached to the aircraft, watercraft or "auto".

12. "Mobile equipment" means any of the following types of land vehicles, including any attached machinery or equipment:

- a. Bulldozers, farm machinery, forklifts and other vehicles designed for use principally off public roads;
- b. Vehicles maintained for use solely on or next to premises you own or rent;
- c. Vehicles that travel on crawler treads;
- d. Vehicles, whether self-propelled or not, maintained primarily to provide mobility to permanently mounted:
  - (1) Power cranes, shovels, loaders, diggers or drills; or
  - (2) Road construction or resurfacing equipment such as graders, scrapers or rollers;
- e. Vehicles not described in Paragraph a., b., c. or d. above that are not self-propelled and are maintained primarily to provide mobility to permanently attached equipment of the following types:
  - (1) Air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment; or
  - (2) Cherry pickers and similar devices used to raise or lower workers;
- f. Vehicles not described in Paragraph a., b., c. or d. above maintained primarily for purposes other than the transportation of persons or cargo.

However, self-propelled vehicles with the following types of permanently attached equipment are not "mobile equipment" but will be considered "autos":

- (1) Equipment designed primarily for:
  - (a) Snow removal;
  - (b) Road maintenance, but not construction or resurfacing; or
  - (c) Street cleaning;
- (2) Cherry pickers and similar devices mounted on automobile or truck chassis and used to raise or lower workers; and
- (3) Air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment.

However, "mobile equipment" does not include any land vehicles that are subject to a compulsory or financial responsibility law or other motor vehicle insurance law where it is licensed or principally garaged. Land vehicles subject to a compulsory or financial responsibility law or other motor vehicle insurance law are considered "autos".

13. "Occurrence" means an accident, including continuous or repeated exposure to substantially the same general harmful conditions.
14. "Personal and advertising injury" means injury, including consequential "bodily injury", arising out of one or more of the following offenses:
  - a. False arrest, detention or imprisonment;
  - b. Malicious prosecution;
  - c. The wrongful eviction from, wrongful entry into, or invasion of the right of private occupancy of a room, dwelling or premises that a person occupies, committed by or on behalf of its owner, landlord or lessor;
  - d. Oral or written publication, in any manner, of material that slanders or libels a person or organization or disparages a person's or organization's goods, products or services;
  - e. Oral or written publication, in any manner, of material that violates a person's right of privacy;
  - f. The use of another's advertising idea in your "advertisement"; or
  - g. Infringing upon another's copyright, trade dress or slogan in your "advertisement".
15. "Pollutants" mean any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled, reconditioned or reclaimed.

**16. "Products-completed operations hazard":**

- a. Includes all "bodily injury" and "property damage" occurring away from premises you own or rent and arising out of "your product" or "your work" except:

- (1) Products that are still in your physical possession; or
- (2) Work that has not yet been completed or abandoned. However, "your work" will be deemed completed at the earliest of the following times:
  - (a) When all of the work called for in your contract has been completed.
  - (b) When all of the work to be done at the job site has been completed if your contract calls for work at more than one job site.
  - (c) When that part of the work done at a job site has been put to its intended use by any person or organization other than another contractor or subcontractor working on the same project.

Work that may need service, maintenance, correction, repair or replacement, but which is otherwise complete, will be treated as completed.

- b. Does not include "bodily injury" or "property damage" arising out of:

- (1) The transportation of property, unless the injury or damage arises out of a condition in or on a vehicle not owned or operated by you, and that condition was created by the "loading or unloading" of that vehicle by any insured;
- (2) The existence of tools, uninstalled equipment or abandoned or unused materials; or
- (3) Products or operations for which the classification, listed in the Declarations or in a policy Schedule, states that products-completed operations are subject to the General Aggregate Limit.

**17. "Property damage" means:**

- a. Physical injury to tangible property, including all resulting loss of use of that property. All such loss of use shall be deemed to occur at the time of the physical injury that caused it; or
- b. Loss of use of tangible property that is not physically injured. All such loss of use shall be deemed to occur at the time of the "occurrence" that caused it.

For the purposes of this insurance, electronic data is not tangible property.



As used in this definition, electronic data means information, facts or programs stored as or on, created or used on, or transmitted to or from computer software, including systems and applications software, hard or floppy disks, CD-ROMs, tapes, drives, cells, data processing devices or any other media which are used with electronically controlled equipment.

18. "Suit" means a civil proceeding in which damages because of "bodily injury", "property damage" or "personal and advertising injury" to which this insurance applies are alleged. "Suit" includes:

- a. An arbitration proceeding in which such damages are claimed and to which the insured must submit or does submit with our consent; or
- b. Any other alternative dispute resolution proceeding in which such damages are claimed and to which the insured submits with our consent.

19. "Temporary worker" means a person who is furnished to you to substitute for a permanent "employee" on leave or to meet seasonal or short-term workload conditions.

20. "Volunteer worker" means a person who is not your "employee", and who donates his or her work and acts at the direction of and within the scope of duties determined by you, and is not paid a fee, salary or other compensation by you or anyone else for their work performed for you.

21. "Your product":

a. Means:

- (1) Any goods or products, other than real property, manufactured, sold, handled, distributed or disposed of by:
  - (a) You;
  - (b) Others trading under your name; or
  - (c) A person or organization whose business or assets you have acquired; and
- (2) Containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products.

b. Includes:

- (1) Warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of "your product"; and
- (2) The providing of or failure to provide warnings or instructions.

c. Does not include vending machines or other property rented to or located for the use of others but not sold.

22. "Your work":

a. Means:

- (1) Work or operations performed by you or on your behalf; and
- (2) Materials, parts or equipment furnished in connection with such work or operations.

b. Includes:

- (1) Warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of "your work"; and
- (2) The providing of or failure to provide warnings or instructions.

**COMMERCIAL GENERAL LIABILITY**  
**NSG 10 01 10 15**

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

## POLARIS A – GENERAL LIABILITY EXTENSION

This endorsement modifies insurance provided under the following:

### COMMERCIAL GENERAL LIABILITY COVERAGE FORM

The following Schedule lists the coverage extensions provided by this endorsement. The descriptions, other than limit amounts, provided in the Schedule are intended for informational purposes only and do not form a part of the policy. Refer to the individual provisions to determine the extent of your coverage. In the event that no limit is shown in the Schedule, the applicable limit in the General Liability Coverage Part Declarations, or the policy to which this endorsement is attached, will apply.

### SCHEDULE

| COVERAGE  | LIMITS/DESCRIPTION   |
|---|--|
| Additional Insured - Broad Form Vendors   | Automatically includes vendors when required by a written contract   |
| Additional Insured - by Contract, Agreement or Permit relating to:<br>➤ Work performed by you<br>➤ Premises you own, rent, lease or occupy<br>➤ Equipment you lease | Automatically includes certain entities with whom the Named Insured contracts when required by a written contract                                    |
| Aggregate Limit - Per Location  | Provides per location aggregates   |
| Blanket Waiver of Subrogation   | Waives Insurer's right of subrogation if Named Insured has waived such rights in a written contract  |
| Bodily Injury Redefined   | Includes resultant mental anguish in the definition of "bodily injury"   |
| Broadened Named Insured   | Entities in which the Named Insured holds a majority interest granted short-term Named Insured status  |
| Broadened Property Damage -<br>➤ Borrowed Equipment Limit<br>➤ Customers' Goods Limit<br>➤ Use of Elevators Limit   | \$ 25,000 per "occurrence"<br>\$ 25,000 per "occurrence"<br>\$ 25,000 per "occurrence"   |
| Broadened Damage To Premises Rented To You  | Extends broadened "all risk" property damage to rented premises beyond seven days.   |
| Coverage Territory  | Extends coverage territory to worldwide for suites brought in the U.S., its possessions or territories, Canada or Puerto Rico.                       |
| Duties in Event of Occurrence, Claim or Suit  | Provides more liberal claim reporting condition  |
| Expected or Intended Injury Exclusion Modified  | Exception extended to cover property damage  |
| Incidental Medical Malpractice  | Medical professional as insureds   |
| Medical Payments  | Extends the time within which expenses are incurred \$10,000   |
| Newly Acquired or Formed Organizations  | Provides automatic coverage for newly acquired organizations which do not have other insurance coverage until the end of the policy period           |
| Non-Owned Aircraft<br>Non-Owned Watercraft  | Exception to the Aircraft and Watercraft exclusion extended to provide additional coverage   |
| Personal and Advertising Injury   | Adds limited coverage for discrimination   |
| Product Recall Expense  | Product Recall Aggregate Limit \$50,000<br>Each Product Recall Limit \$25,000<br>Product Recall Deductible   |
| Supplementary Payments Increased Limits   | Cost of Bail Bonds/Appeals Bonds – Up to the Limit of Insurance, subject to a \$1,000,000 aggregate Reasonable Expenses Incurred Limit \$1,500 a day |

**I. ADDITIONAL INSURED - BROAD FORM VENDORS**

- A. Section II - Who Is An Insured is amended to include as an additional insured any person or organization referred to below as vendor to whom you agreed in a written contract or written agreement to provide insurance, but only with respect to "bodily injury" or "property damage" arising out of "your products" which are distributed or sold in the regular course of the vendor's business, subject to the following additional exclusions:

This provision does not apply to:

1. "Bodily injury" or "property damage" for which the vendor is obligated to pay damages by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for damages that the vendor would have in the absence of the contract or agreement;
2. Any express warranty unauthorized by you;
3. Any physical or chemical change in the product made intentionally by the vendor;
4. Repackaging, except when unpacked solely for the purpose of inspection, demonstration, testing or the substitution of parts under instructions from the manufacturer, and then repackaged in the original container;
5. Any failure to make such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the products;
6. Demonstration, installation, servicing or repair operations, except such operations performed at the vendor's premises in connection with the sale of the product;
7. Products which, after distribution or sale by you, have been labeled or relabeled or used as a container, part or ingredient of any other thing or substance by or for the vendor;
8. "Bodily injury" or "property damage" arising out of the sole negligence of the vendor for its own acts or omissions or those of its employees or anyone else acting on its behalf. However, this exclusion does not apply to:
  - a. The exceptions contained in Subparagraphs 4. or 6. above; or
  - b. Such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the products; or
9. Any person or organization if the "products-completed operations hazard" is excluded either by the provisions of the Coverage Form or by endorsement.

- B. This insurance does not apply to:

1. "Bodily injury" or "property damage" for which the vendor is obligated to pay damages by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for damages that the vendor would have in the absence of the contract or agreement;
2. Any express warranty unauthorized by you;
3. Any physical or chemical change in the product made intentionally by the vendor;
4. Repackaging, except when unpacked solely for the purpose of inspection, demonstration, testing, or the substitution of parts under instructions from the manufacturer, and then repackaged in the original container;
5. Any failure to make such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the products;
6. Demonstration, installation, servicing or repair operations, except such operations performed at the vendor's premises in connection with the sale of the product;
7. Products which, after distribution or sale by you, have been labeled or relabeled or used as a container, part or ingredient of any other thing or substance by or for the vendor;
8. "Bodily injury" or "property damage" arising out of the sole negligence of the vendor for its own acts or omissions or those of its employees or anyone else acting on its behalf. However, this exclusion does not apply to:
  - a. The exceptions contained in Subparagraphs 4. or 6.; or



- b. Such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the products.
- 9. Any insured person or organization, from whom you have acquired such products, or any ingredient, part or container, entering into, accompanying or containing such products.
- C. Limits of Insurance applicable to the additional insured are the lesser of i) those specified in the aforementioned contract or agreement or ii) those shown in the Declarations and fix the most we will pay regardless of the number of:
  - 1. Insureds;
  - 2. Claims made or "suits" brought; or
  - 3. Persons or organizations making claims or bringing "suits".

These Limits of Insurance are included in and not in addition to the Limits of Insurance shown in the Declarations.

## II. ADDITIONAL INSURED - CONTRACT, AGREEMENT OR PERMIT

- A. Section II - Who Is An Insured is amended to include as an additional insured any person or organization to whom you agreed in a written contract, written agreement or permit to provide insurance such as is afforded under this Coverage Part, but only with respect to liability for "bodily injury", "property damage" or "personal and advertising injury" caused, in whole or in part, by your acts or omissions or the acts or omissions of those acting on your behalf:
  - 1. In the performance of "your work" for the additional insured at the location designated in the contract, agreement or permit;
  - 2. In the maintenance, operation or use of equipment leased to you by such person or organization; or
  - 3. In connection with premises you own, rent, lease or occupy.

This insurance applies on a primary basis or on a primary and non-contributory basis if required in the aforementioned contract, agreement or permit.

- B. The insurance provided to the additional insured herein is limited. This insurance does not apply:
  - 1. Unless:
    - a. The written contract, written agreement or permit is currently in effect or becomes effective during the term of this policy; and
    - b. The written contract or written agreement was executed or permit issued prior to the time that the "bodily injury", "property damage" or "personal and advertising injury" commenced;
  - 2. To any person or organization included as an insured under the Additional Insured - Broad Form Vendors provision of this endorsement;
  - 3. To any person or organization included as an insured by an endorsement issued by us and made part of this Coverage Part;
  - 4. To any person or organization if the "bodily injury", "property damage", or "personal and advertising injury" arises out of the rendering of or failure to render any professional architectural, engineering or surveying services by or for you including:
    - a. The preparing, approving, or failing to prepare or approve, maps, shop drawings, opinions, reports, surveys, field orders, change orders or drawings and specifications; or
    - b. Supervisory, inspection, architectural or engineering activities;
  - 5. To any:
    - a. Lessor of equipment after the equipment lease expires;
    - b. Owners or other interests from whom land has been leased; or
    - c. Managers or lessors of premises if:
      - (1) The "occurrence" takes place after you cease to be a tenant in that premises; or
      - (2) The "bodily injury", "property damage", "personal and advertising injury" arises out of structural alterations, new construction or demolition operations performed by or on behalf of the manager or lessor; or
  - 6. To "bodily injury", or "property damage" occurring after:
    - a. All work on the project (other than service, maintenance or repairs) to be performed by or on behalf of the additional insured at the site of the covered operations has been completed; or

- b. That portion of "your work" out of which the injury or damage arises has been put to its intended use by any person or organization other than another contractor or subcontractor engaged in performing operations for a principal as part of the same project.
- C. Limits of Insurance applicable to the additional insured are the lesser of i) those specified in the aforementioned contract, agreement or permit or ii) those shown in the Declarations and fix the most we will pay regardless of the number of:

1. Insureds;
2. Claims made or "suits" brought; or
3. Persons or organizations making claims or bringing "suits".

These Limits of Insurance are included in and not in addition to the Limits of Insurance shown in the Declarations.

### III. AGGREGATE LIMIT PER LOCATION

A. Under Section III - Limits Of Insurance, the General Aggregate Limit applies separately to each of your "locations" owned by or rented or leased to you.

B. The following is added to Section V - Definitions:

"Location" means premises involving the same or connecting lots, or premises whose connection is interrupted only by a street, roadway, waterway or right-of-way of a railroad.

### IV. BLANKET WAIVER OF SUBROGATION

The following is added to the **Transfer Of Rights Of Recovery Against Others To Us** condition in Section IV - Commercial General Liability Conditions:

We will waive any right of recovery we may have against any person or organization because of payments we make for injury or damage arising out of your ongoing operations done under a written contract or agreement with that person or organization and included in "your work" or the "products-completed operations hazard". This waiver applies only to persons or organizations with which you have a written contract, executed prior to the "bodily injury" or "property damage" that requires you to waive your rights of recovery.

### V. BODILY INJURY REDEFINED - MENTAL ANGUISH

The "bodily injury" definition in Section V - Definitions is replaced by the following:

"Bodily injury" means bodily injury, sickness, or disease sustained by a person. This includes mental anguish resulting from bodily injury, sickness or disease.

### VI. BROADENED NAMED INSURED

Section II - Who Is An Insured is amended to include as an insured the following:

Any organization which is a legally formed entity and in which you own a financial interest of more than fifty percent (50%) of the interest entitled to vote generally in the election of the governing body of such organization will be a Named Insured on the effective date of this endorsement until the earlier of:

- A. The 180<sup>th</sup> day after the issuance of this endorsement; or
- B. The end of the policy period,

provided there is no other similar insurance available to that organization. The insurance afforded herein does not apply to any entity which is also an insured under another policy or would be an insured under such policy but for its termination or the exhaustion of its limits of insurance.

### VII. BROADENED PROPERTY DAMAGE - RENTED PREMISES, BORROWED EQUIPMENT, CUSTOMERS' GOODS AND USE OF ELEVATORS

A. Section I - Coverages, Coverage A - Bodily Injury And Property Damage Liability, paragraph 2. Exclusions, exclusion j. **Damage To Property** is replaced by the following:

#### j. Damage To Property

"Property damage" to:

- (1) Property you own, rent, or occupy, including any costs or expenses incurred by you, or any other person, organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property;
- (2) Premises you sell, give away or abandon, if the "property damage" arises out of any part of those premises;
- (3) Property loaned to you;
- (4) Personal property in the care, custody or control of the insured;
- (5) That particular part of real property on which you or any contractors or subcontractors working directly or indirectly on your behalf are performing operations, if the "property damage" arises out of those operations; or

- (6) That particular part of any property that must be restored, repaired or replaced because "your work" was incorrectly performed on it.

Paragraphs (1), (3) and (4) of this exclusion do not apply "property damage" (other than damage by fire) to premises, including the contents of such premises, rented to you. A separate limit of insurance applies to Damage To Premises Rented To You as described in Section III - Limits Of Insurance.

Paragraph (2) of this exclusion does not apply if the premises are "your work" and were never occupied, rented or held for rental by you.

Paragraphs (3), (4) and (5) of this exclusion do not apply to "property damage" to "customers' goods" while on your premises, subject to the Broadened Property Damage - Customers' Goods Limit shown in the **SCHEDULE**.

Paragraphs (3), (4) and (5) of this exclusion do not apply to "property damage" arising from the use of elevators at premises you own, rent, lease or occupy, subject to the Use of Elevators Limit for the Broadened Property Damage shown in the **SCHEDULE**.

Paragraphs (3), (4), (5) and (6) of this exclusion do not apply to liability assumed under a sidetrack agreement.

Paragraph (4) does not apply to "property damage" to equipment you borrow while at a job site and provided it is not being used by anyone to perform operations at the time of loss, subject to the Borrowed Equipment Limit for the Broadened Property Damage shown in the **SCHEDULE**.

Paragraph (6) of this exclusion does not apply to "property damage" included in the "products-completed operations hazard".

**B. The following is added to Section V - Definitions:**

"Customers' goods means goods of your customers on your premises for the purposes of being:

1. Repaired; or
2. Used in your manufacturing process.

**C. The insurance afforded by this provision is excess over any other valid and collectible property insurance (including any deductible) available to the insured whether such insurance is primary, excess, contingent or on any other basis. We will make payments in accordance with the Excess Insurance provision of the Other Insurance condition in the Commercial General Liability Conditions.**

**VIII. COVERAGE TERRITORY - WORLDWIDE**

The "coverage territory" definition in Section V - Definitions is replaced by the following:

"Coverage territory" means anywhere in the world. However, the insured's responsibility to pay damages must be determined in a settlement to which we agree or in a "suit" on the merits brought within the United States of America (including its territories and possessions), Puerto Rico or Canada.

**IX. DUTIES IN THE EVENT OF OCCURRENCE, OFFENSE, CLAIM OR SUIT**

The following is added to Section IV - Conditions, Duties In The Event Of Occurrence, Claim Or Suit:

**A. The requirements that you must**

1. Notify us, as soon as practicable, of an "occurrence", offense, claim or "suit"; and
  2. Send us documents concerning a claim or "suit"
- apply only-when such "occurrence", offense, claim or "suit" is known to:
- a. You, if you are an individual;
  - b. A partner, if you are a partnership;
  - c. An executive officer of the corporation or insurance manager, if you are a corporation; or
  - d. A manager, if you are a limited liability company.

**B. The requirement that you must notify us as soon as practicable of an "occurrence" or an offense that may result in a claim does not apply if you report an "occurrence" to your workers compensation insurer which later develops into a liability claim for which coverage is provided by this policy. However, as soon as you have definite knowledge that the particular "occurrence" is a liability claim rather than a workers' compensation claim, you must comply with the Duties In The Event Of Occurrence, Offense, Claim Or Suit condition in Section IV - Commercial General Liability Conditions.**

**X. EXPECTED OR INTENDED INJURY (PROPERTY DAMAGE)**

Section I - Coverages, Coverage A - Bodily Injury And Property Damage Liability, paragraph 2. Exclusions, exclusion a. **Expected Or Intended Injury** is replaced by the following:

"Bodily injury" or "property damage" expected or intended from the standpoint of the insured. This exclusion does not apply to "bodily injury" or "property damage" resulting from the use of reasonable force to protect persons or property.

**XI. INCIDENTAL MEDICAL MALPRACTICE - EMPLOYED PHYSICIANS, NURSES, EMT'S AND PARAMEDICS****A. Section II - Who Is An Insured, paragraph 2.a.(1)(d) is replaced by the following:**

- (d) Arising out of his or her providing or failing to provide professional health care services; provided. However that this does not apply to a physician, dentist, nurse, emergency medical technician or paramedic employed by you if you are not engaged in the business or occupation of providing medical, paramedical, surgical, dental, x-ray or nursing services.

**B. The insurance afforded by this provision is excess over any other valid and collectible insurance whether such insurance is primary, excess, contingent or on any other basis. We will make payments in accordance with the Excess Insurance provision of the Other Insurance condition in the Commercial General Liability Conditions.****XII. MEDICAL PAYMENTS - INCREASED LIMITS AND TIME PERIOD****A. This provision only applies if a limit is shown for Medical Payments in the SCHEDULE.****B. Section I - Coverages, Coverage C - Medical Payments, paragraph 1. Insuring Agreement, item (b) is replaced by the following:**

- (b) The expenses are incurred and reported to us within four years of the date of the accident; and

**C. The Medical Payments Limit is shown in the SCHEDULE.****XIII. NEWLY FORMED OR ACQUIRED ORGANIZATIONS****A. Section II - Who Is An Insured, paragraph 3. is replaced by the following:**

3. Any organization you newly acquire or legally form, other than a partnership or joint venture, and over which you maintain ownership or majority interest, will qualify as a Named Insured if there is no other similar insurance available to that organization. However:

- a. Coverage under this provision is afforded only until the end of the policy period during which you acquire or form the organization;
- b. Coverage A does not apply to "bodily injury" or "property damage" that occurred before you acquired or formed the organization; and
- c. Coverage B does not apply to "personal and advertising injury" arising out of an offense committed before you acquired or formed the organization.

**B. The last paragraph of Section II - Who Is An Insured is replaced by the following:**

No person or organization is an insured with respect to the conduct of any current or past partnership, joint venture or limited liability company that is not shown as a Named Insured in the Declarations. Notwithstanding the foregoing, this does not apply to any organization you newly acquire or legally form and to which paragraph 3. of Section II - Who Is An Insured applies.

**XIV. NON-OWNED AIRCRAFT AND WATERCRAFT****A. Section I - Coverages, Coverage A - Bodily Injury And Property Damage Liability, paragraph 2. Exclusions, exclusion g. Aircraft, Auto Or Watercraft is replaced by the following:****g. Aircraft, Auto Or Watercraft**

"Bodily injury" or "property damage" arising out of the ownership, maintenance, use or entrustment to others of any aircraft, "auto" or watercraft owned or operated by or rented or loaned to any insured. Use includes operation and "loading or unloading".

This exclusion applies even if the claims against any insured allege negligence or other wrongdoing in the supervision, hiring, employment, training or monitoring of others by that insured, if the "occurrence" which caused the "bodily injury" or "property damage" involved the ownership, maintenance, use or entrustment to others of any aircraft, "auto" or watercraft that is owned or operated by or rented or loaned to any insured.

This exclusion does not apply to:

- (1) A watercraft while ashore on premises you own or rent;
- (2) A watercraft you do not own that is:
  - (a) Less than 75 feet long; and
  - (b) Not being used to carry persons or property for a charge;
- (3) Parking an "auto" on, or on the ways next to, premises you own or rent, provided the "auto" is not owned by or rented or loaned to you or the insured;
- (4) Liability assumed under any "insured contract" for the ownership, maintenance or use of aircraft or watercraft; or
- (5) "Bodily injury" or "property damage" arising out of:

- (a) The operation of machinery or equipment that is attached to, or part of, a land vehicle that would qualify under the definition of "mobile equipment" if it were not subject to a compulsory or financial responsibility law or other motor vehicle insurance law where it is licensed or principally garaged; or
- (b) The operation of any of the machinery or equipment listed in Paragraph f.(2) or f.(3) of the definition of "mobile equipment".
- (6) An aircraft that is:
  - (a) Hired, chartered or loaned with a paid crew; and
  - (b) Not owned by any insured.
- B. Section II - Who Is An Insured is amended to include as an insured for any watercraft that is covered by this policy, any person who, with your expressed or implied consent, either uses or is responsible for the use of a watercraft. However, no person or organization is an insured with respect to:
  - 1. "Bodily injury" to a co-"employee" of the person operating the watercraft; or
  - 2. "Property damage" to property owned by, rented to, in the charge of or occupied by you or the employer of any person who is an insured under this provision.
- C. The insurance afforded by this provision is excess over any other valid and collectible insurance (including any deductible or Self Insured Retention) available to the insured, whether such insurance is primary, excess, contingent or on any other basis. We will make payments in accordance with the Excess Insurance provision of the Other Insurance condition in the Commercial General Liability Conditions.

#### **XV. PERSONAL AND ADVERTISING INJURY**

- A. The following is added to the "personal and advertising injury" definition in Section V - Definitions:
  - h. Discrimination because of race, color, creed, national origin, age, sex or physical disability, where insurance therefore is not prohibited by law, but only if such discrimination is:
    - (1) Not done intentionally by or at the direction of:
      - (a) The insured; or
      - (b) Any executive officer, director, stockholder, partner or member of the insured staff; and
    - (2) Not directly or indirectly related to the employment, prospective employment or termination of employment of any person or persons by any insured.
- B. The insurance afforded under this provision does not apply to fines or penalties, or that portion of any award or judgment caused by trebling or multiplication of actual damages under state or federal law.
- C. This provision does not apply if Coverage B - Personal And Advertising Injury Liability is otherwise excluded under this Coverage Form.

#### **XVI. PRODUCT RECALL EXPENSE**

##### **A. Product Recall Insuring Agreement**

We will reimburse you for covered "product recall expense" that you paid in excess of the Product Recall Deductible shown in the **SCHEDULE**.

- 1. A "product recall" is covered if:
  - a. The "product recall" is made necessary because:
    - (1) You make a reasonable and good faith determination; or
    - (2) Any governmental body makes a ruling that the use or consumption of "your product" has a substantial probability of causing "bodily injury" or "property damage" solely because of a known or suspected defect, inadequacy or dangerous condition in "your product"; or
  - b. The "product recall" is made necessary because of "product tampering".
- 2. This insurance applies to a "product recall" only if:
  - a. The "product recall" relates solely to a recall of "your product" in the United States of America (including its territories and possessions), Puerto Rico and Canada; and
  - b. Prior to the inception date or prior to the time "your product" left your control, the insured had no knowledge of any actual, alleged, suspected or threatened defect, inadequacy or dangerous condition in "your product" or any resulting "claim", "suit" or governmental proceeding whether or not notice of any such "product recall", "claim" or "suit" was furnished to any other insurer.
- 3. This insurance applies only to a "product recall" that commences during the policy period.

##### **B. Exclusions**



1. Section I - Coverages, Coverage A - Bodily Injury And Property Damage Liability, paragraph 2. **Exclusions**, item n. **Recall Of Products, Work Or Impaired Property** does not apply to the coverage provided under this provision.
  2. The following exclusions in Section I - Coverages, Coverage A - Bodily Injury And Property Damage Liability, paragraph 2. **Exclusions** apply to coverage under this provision:
    - a. Exclusion b. **Contractual Liability**; and
    - b. Exclusion f. **Pollution**.
  3. Further, this insurance does not apply to "product recall" arising out of, related to or resulting from any of the following:
    - a. Failure of "your product" to accomplish its intended purpose;
    - b. Deterioration, wear and tear or decomposition of "your product";
    - c. Violation of any government regulation;
    - d. "Your product" contains or has come into contact with a hazardous substance or material banned by any governmental entity;
    - e. Dishonesty by You, Your Officers and Employees;
    - f. Products Recalled between Insured Entities You Control within Your Organization;
    - g. Inclusion in your product of any of the following:
      - (1) Asbestos;
      - (2) Lead; or
      - (3) Silica;
    - h. Expiration of the shelf life of "your product"; or
    - i. Third party damages, fines or penalties.
- C. With respect to the coverage provided under this provision, the following are added to Section V - Definitions:
1. "Product recall" means the withdrawal, recall, inspection, removal or disposal of:
    - a. "Your product"; or
    - b. Any property of which "your product" forms a part from the market or from use by any person or organization.
  2. "Product recall expense" means:
    - a. The following necessary and reasonable expenses you incur exclusively for the purpose of recalling "your product":
      - (1) For communications, including radio or television announcements or printed advertisements including stationery, envelopes and postage;
      - (2) For shipping the recalled products from any purchaser, distributor or user to the place or places designated by you;
      - (3) For remuneration paid to your regular "employees" for necessary overtime;
      - (4) For hiring additional persons, other than your regular "employees";
      - (5) Incurred by "employees", including transportation and accommodations;
      - (6) To rent additional warehouse or storage space; or
      - (7) For disposal of "your products", but only to the extent that specific methods of destruction other than those employed for trash discarding or disposal are required to avoid "bodily injury" or "property damage" as a result of such disposal, but "product recall expenses" does not include costs of regaining your market share, goodwill, revenue or profit.
    - b. "Product recall expense" does not include any expenses resulting from:
      - (1) Failure of any product to accomplish its intended purpose;
      - (2) Breach of warranties of fitness, quality, durability or performance;
      - (3) Loss of customer approval, or any cost incurred to regain customer approval;
      - (4) Redistribution or replacement of "your product" which has been recalled by like products or substitutes;
      - (5) Caprice or whim of the insured;
      - (6) A condition likely to cause loss of which any insured knew or had reason to know at the inception of this insurance; and

(7) Recall of "your products" that have no known or suspected defect solely because of a known suspected defect in another of "your products" has been found.

3. "Product tampering" means any actual, alleged or threatened, intentional, or malicious alteration or contamination of "your product", whether or not by an employee that renders it unfit or dangerous for use or consumption, or conveys that impression to the public.

**XVII. SUPPLEMENTARY PAYMENTS - INCREASED LIMITS**

Section I - Coverages, Supplementary Payments - Coverages A And B, paragraph 1. is replaced by the following:

1. We will pay, with respect to any claim we investigate or settle, or any "suit" against an insured we defend:
  - a. All expenses we incur.
  - b. For cost of bail bonds required because of accidents or traffic law violations arising out of the use of any vehicle to which the Bodily Injury Liability Coverage applies up to the Bodily Injury Limit of Insurance, subject to an annual aggregate of \$1,000,000. We do not have to furnish these bonds.
  - c. The cost of bonds to release attachments up to the applicable Per Occurrence Limit of Insurance for Coverage A or Coverage B, whichever applies to the claim, subject to an annual aggregate of \$1,000,000, but only for bond amounts within the applicable limit of insurance. We do not have to furnish these bonds.
  - d. All reasonable expenses incurred by the insured at our request to assist us in the investigation or defense of the claim or "suit", including actual loss of earnings up to the Reasonable Expenses Incurred Limit shown in the **SCHEDULE** because of time off from work.
  - e. All court costs taxed against the insured in the "suit". However, these payments do not include attorneys' fees or attorneys' expenses taxed against the insured.
  - f. Prejudgment interest awarded against the insured on that part of the judgment we pay. If we make an offer to pay the applicable limit of insurance, we will not pay any prejudgment interest based on that period of time after the offer.
  - g. All interest on the full amount of any judgment that accrues after entry of the judgment and before we have paid, offered to pay, or deposited in court the part of the judgment that is within the applicable limit of insurance.

These payments will not reduce the limits of insurance.

COMMERCIAL GENERAL LIABILITY  
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**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

## **EXCLUSION – ASBESTOS**

This endorsement modifies coverage provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE FORM

This insurance does not apply to any liability, damages or loss arising out of the actual, alleged, suspected or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of "asbestos".

"Asbestos" means the mineral in any form, or any product containing asbestos.

All other terms of the policy remain unchanged.



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THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

## RESTRICTION OF COVERAGE – LIFE SCIENCES

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE FORM

This endorsement contains the following restrictions of coverage:

Exclusion and Redefinition of Products-Completed Operations Hazard, Your Product and Your Work  
Health Care Services Exclusion  
Professional Liability Exclusion  
Advertising Injury and Personal Injury Exclusion  
Contractual Liability Limitation

**I. SECTION I — COVERAGES, COVERAGE A BODILY INJURY AND PROPERTY DAMAGE LIABILITY, 2. Exclusions** is amended to include the following:

**r. Products-Completed Operations Hazard**

1. This insurance does not apply to any injury, damage, loss, cost or expense, including but not limited to "bodily injury" or "property damage" arising out of, included within or in any way related to the "products-completed operations hazard".

**s. Health Care And "Life Science Fields of Science" Services**

1. This insurance does not apply to any injury, damage, loss, cost or expense, including but not limited to "bodily injury", "property damage" or "personal and advertising injury" arising out of or in any way related to:
  - a. Medical, surgical, dental, x-ray or nursing service, treatment, products, advice or instruction;
  - b. Any health or therapeutic service, treatment, product, advice or instruction;
  - c. The providing, or failure to provide, any service, treatment, advice or instruction for the purpose of appearance or skin enhancement, hair removal or replacement, or personal grooming;
  - d. The furnishing or dispensing of drugs or medical, dental or surgical supplies, products or appliances;
  - e. The handling or treatment of dead bodies, including autopsies, organ donation or other procedures; or.
  - f. Use of any medical equipment or medical device whether or not any of the foregoing:
    - (1) Are performed by you or by others; or
    - (2) Arise out of or are in any way related to the "products-completed operations hazard".

2. This insurance does not apply to Incidental Malpractice of employed nurses, medical technicians or paramedics employed by you and this exclusion supersedes any grant of coverage elsewhere in the policy.

**t. Professional Liability**

1. This insurance does not apply to any injury, damage, loss, cost or expense, including but not limited to "bodily injury", 'property damage', or 'personal and advertising injury' arising out of or in any way related to the actual or alleged rendering of or failure to render any professional services or ancillary support services. This exclusion supersedes any grant of coverage elsewhere in the policy.

The rendering of "professional services" includes, but is not limited to:

- a. All "administrative, ministerial or supervised activity", directly or indirectly related to the professional service; and
  - b. All equipment directly or indirectly related to or involved with the performance of the specific professional service.
2. This exclusion applies whether or not the professional services are performed by or include:
    - a. Any insured;
    - b. Any person or organization for which any insured is legally responsible; or
    - c. Liability assumed by any insured under any contract or agreement whether or not:
      - (1) Remuneration is received; or
      - (2) Such services are directly, indirectly, incidentally, or not at all related to the "products completed operations hazard" or any other operations or activities.
  3. This exclusion does not apply to the use of defibrillators in the course of providing first aid services, including cardiopulmonary resuscitation, during a medical emergency and for which no remuneration is demanded or received.

**II. SECTION I - COVERAGES, COVERAGE B PERSONAL AND ADVERTISING INJURY LIABILITY, 2. Exclusions** is amended to include the following:

**q. "Clinical Trial(s)"**

Personal and advertising injury arising out of a 'clinical trial' when conducted by you or on your behalf, on or away from your premises, arising out of your business.

**r. Right of Privacy**

Personal and advertising injury arising out of the oral or written publication, in any manner, of material that violates a person's right of privacy, including any release of patient information.

**III. SECTION V — DEFINITIONS** are amended to include the following changes:

Item 9. is deleted in its entirety and replaced with the following definition:

9. "Insured contract" means:

- a. A contract for a lease of premises. However, that portion of the contract for a lease of premises that indemnifies any person or organizations for damage by fire to premises while rented to you or temporarily occupied by you with permission of the owner is not an "insured contract";
- b. A sidetrack agreement;
- c. Any easement or license agreement, except in connection with construction or demolition operations on or within 50 feet of a railroad;
- d. An obligation, as required by ordinance, to indemnify a municipality, except in connection with work for a municipality;
- e. An elevator maintenance agreement.

Item 14. e. Oral or written publication, in any manner, of material that violates a person's right of privacy is deleted from the definition of "Personal and advertising injury".

Item 16. is deleted in its entirety and replaced with the following definition:

16. "Products-completed operations hazard" includes any injury or damage arising out of or in any way related to:

- a. "Your product" or "your work" whether or not:
  - (1) Such products or work are on or away from your premises;
  - (2) Possession of such products or work has been relinquished;
  - (3) The product or work is completed or still in progress, or in any stage of trial, design, evaluation, demonstrating or testing;
  - (4) Tools, uninstalled equipment or abandoned or unused materials are present on or away from your premises; or
  - (5) Products or operations for which the classification, listed in the Declarations or in a policy schedule, states that products-completed operations are subject to the General Aggregate Limit;
- b. Any trial, design, evaluation, demonstration or testing whether provided by physicians or others including, but not limited to, "clinical trial(s)" of "your product" or "your work" including, but not limited to the evaluation or testing of drugs, cosmetics, chemical or biological agents, pharmaceuticals, medical devices, surgical devices or dental devices on human, animal or other subjects for any purpose whatsoever;
- c. An error, omission, defect or deficiency in:
  - (1) Any test performed; or
  - (2) Any evaluation or consultation or advice given by or on behalf of any insured;
- d. The reporting of or reliance upon any test performed or any evaluation, consultation or advice given by or on behalf of any insured;
- e. An error, omission, defect or deficiency in experimental data or the interpretation of data; or
- f. Violation of any intellectual property rights, including but not limited to patent, copyright, trademark or service mark, trade name, trade secret or other designation of origin or authenticity in any way related to "your product" or "your work", or the work or product of others.

Item 21. is deleted in its entirety and replaced with the following definition:

**21. "Your product":**

**a. Means:**

- (1) Any goods or products, other than real property, designed, tested, studied, evaluated, manufactured, sold, handled, distributed, licensed or disposed of by:
  - a) You, whether on your own behalf or on behalf of any others
  - b) Others trading under your name; or
  - c) A person or organization whose business or assets you have acquired; or
- (2) Containers (other than vehicles), materials, parts of equipment furnished in connection with, or in any way related to, any of the foregoing in (1) above.

**b. Includes:**

- (1) Warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of "your product";
- (2) Consultations or advice given at any time with respect to the design, fitness, quality, durability, performance or use of "your product";
- (3) The providing of or failure to provide warnings or instructions; and
- (4) Vending machines or other property located for the use of others whether or not sold.

Item 22. is deleted in its entirety and replaced with the following definition:

**22. "Your work":**

**a. Means:**

- (1) Work or operations, including but not limited to design, testing, "clinical trial(s)", demonstrations, studies or evaluations performed by you or on your behalf;
- (2) Materials, parts or equipment furnished in connection with such work or operations.

**b. Includes:**

- (1) Warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of "your work";
- (2) Consultations or advice given at any time with respect to the design, fitness, quality, durability, performance or use of "your work"; and
- (3) The providing of or failure to provide warnings or instructions.

The following definitions have been added:

23. "Administrative, ministerial, or supervised activity" includes, but is not limited to identifying, labeling, typing, mailing or matching of results or reports.
24. "Clinical trial(s)" means any organized study or test that uses human subject to establish the effectiveness, bioequivalence or safety of a pharmaceutical, medical device or therapeutic treatment or diagnostic process.
25. "Life sciences fields of science" means the fields of scientific study, manufacture of and/or delivery of products and/or services that involve the scientific study of living organisms, such as but not limited to, microorganisms, plants, animals, and human

beings and include bioethics, biology, molecular biology and biotechnology and scientific specializations.

26. "Professional Services" means any service, including advice or consultation, which requires, on the part of the person rendering the service, specialized learning, skill, training, licensing or certification, or any service or practice that is controlled by the jurisdiction in which it is practiced or by a professional association.

COMMERCIAL GENERAL LIABILITY  
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THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

**EXCLUSION – PROFESSIONAL SERVICES LIABILITY**

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART

- A. The following is added to Paragraph 2. **Exclusions** of Section I – Coverage A – Bodily Injury And Property Damage Liability and Section I – Coverage B – Personal And Advertising Injury Liability:

This insurance does not apply to:

1. Injuries, damages, claims, "suits", actions or proceedings arising out of any "wrongful act" committed by the insured, or by any person for whom the insured is legally liable, and arising out of the rendering or failure to render "professional services" in the conduct of the insured's business; or
2. Any "costs" resulting directly from any "wrongful act" committed by the insured, or by any person for whom the insured is legally liable, and arising out of the rendering or failure to render "professional services" in the conduct of the insured's business.

- B. Solely with respect to this endorsement, the following are added to Section V – Definitions:

"Costs" means fines, sanctions, statutory penalties, fees and other expenses.

"Professional services" means services including, but not limited to, consulting, offering advice or making recommendations while in the conduct of the insured's business.

"Wrongful act" means any alleged act, error or omission, committed solely in the performance of Professional Services.

POLICY NUMBER: CH17NCP020480-00

COMMERCIAL GENERAL LIABILITY  
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THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

**ADDITIONAL INSURED -- DESIGNATED  
PERSON OR ORGANIZATION**

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART

**SCHEDULE****Name Of Additional Insured Person(s) Or Organization(s):**WELLS FARGO BANK, NATIONAL ASSOCIATION, AS AGENT & ITS SUCCESSORS  
AND/OR ASSIGNSCANTOR FITZGERALD SECURITIES, AS AGENT  
IS ONLY AN ADDITIONAL INSURED WITH RESPECTS TO DEBENTURE  
DATED 21 JULY 2017 BETWEEN PERNIX IRELAND PAIN LIMITED  
AND CANTOR FITZGERALD SECURITIES, AND THE ASSET-BASED CREDIT  
AGREEMENT BETWEEN PERNIX THERAPEUTICS AND CANTOR FITZGERALD  
SECURITIES

Information required to complete this Schedule, if not shown above, will be shown in the Declarations.

**A. Section II – Who Is An Insured** is amended to include as an additional insured the person(s) or organization(s) shown in the Schedule, but only with respect to liability for "bodily injury", "property damage" or "personal and advertising injury" caused, in whole or in part, by your acts or omissions or the acts or omissions of those acting on your behalf:

1. In the performance of your ongoing operations; or
2. In connection with your premises owned by or rented to you.

However:

1. The insurance afforded to such additional insured only applies to the extent permitted by law; and
2. If coverage provided to the additional insured is required by a contract or agreement, the insurance afforded to such additional insured will not be broader than that which you are required by the contract or agreement to provide for such additional insured.

**B. With respect to the insurance afforded to these additional insureds, the following is added to Section III – Limits Of Insurance:**

If coverage provided to the additional insured is required by a contract or agreement, the most we will pay on behalf of the additional insured is the amount of insurance:

1. Required by the contract or agreement; or
2. Available under the applicable Limits of Insurance shown in the Declarations;

whichever is less.

This endorsement shall not increase the applicable Limits of Insurance shown in the Declarations.

COMMERCIAL GENERAL LIABILITY

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**EXCLUSION – PRODUCTS-COMPLETED OPERATIONS  
HAZARD**

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART.

This insurance does not apply to "bodily injury" or "property damage" included within the "products-completed operations hazard".



COMMERCIAL GENERAL LIABILITY  
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THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

**EXCLUSION – ACCESS OR DISCLOSURE OF  
CONFIDENTIAL OR PERSONAL INFORMATION AND  
DATA-RELATED LIABILITY – WITH  
LIMITED BODILY INJURY EXCEPTION**

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART

- A. Exclusion 2.p. of Section I – Coverage A – Bodily Injury And Property Damage Liability is replaced by the following:

**2. Exclusions**

This insurance does not apply to:

- p. **Access Or Disclosure Of Confidential Or Personal Information And Data-related Liability**

Damages arising out of:

- (1) Any access to or disclosure of any person's or organization's confidential or personal information, including patents, trade secrets, processing methods, customer lists, financial information, credit card information, health information or any other type of nonpublic information; or
- (2) The loss of, loss of use of, damage to, corruption of, inability to access, or inability to manipulate electronic data.

This exclusion applies even if damages are claimed for notification costs, credit monitoring expenses, forensic expenses, public relations expenses or any other loss, cost or expense incurred by you or others arising out of that which is described in Paragraph (1) or (2) above.

However, unless Paragraph (1) above applies, this exclusion does not apply to damages because of "bodily injury".

As used in this exclusion, electronic data means information, facts or programs stored as or on, created or used on, or transmitted to or from computer software, including systems and applications software, hard or floppy disks, CD-ROMs, tapes, drives, cells, data processing devices or any other media which are used with electronically controlled equipment.

- B. The following is added to Paragraph 2. **Exclusions of Section I – Coverage B – Personal And Advertising Injury Liability:**

**2. Exclusions**

This insurance does not apply to:

**Access Or Disclosure Of Confidential Or Personal Information**

"Personal and advertising injury" arising out of any access to or disclosure of any person's or organization's confidential or personal information, including patents, trade secrets, processing methods, customer lists, financial information, credit card information, health information or any other type of nonpublic information.

This exclusion applies even if damages are claimed for notification costs, credit monitoring expenses, forensic expenses, public relations expenses or any other loss, cost or expense incurred by you or others arising out of any access to or disclosure of any person's or organization's confidential or personal information.

COMMERCIAL GENERAL LIABILITY  
CG 21 47 12 07

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

## EMPLOYMENT-RELATED PRACTICES EXCLUSION

This endorsement modifies insurance provided under the following:

### COMMERCIAL GENERAL LIABILITY COVERAGE PART

**A. The following exclusion is added to Paragraph 2., Exclusions of Section I – Coverage A – Bodily Injury And Property Damage Liability:**

This insurance does not apply to:

"Bodily injury" to:

- (1) A person arising out of any:
  - (a) Refusal to employ that person;
  - (b) Termination of that person's employment; or
  - (c) Employment-related practices, policies, acts or omissions, such as coercion, demotion, evaluation, reassignment, discipline, defamation, harassment, humiliation, discrimination or malicious prosecution directed at that person; or
- (2) The spouse, child, parent, brother or sister of that person as a consequence of "bodily injury" to that person at whom any of the employment-related practices described in Paragraphs (a), (b), or (c) above is directed.

This exclusion applies:

- (1) Whether the injury-causing event described in Paragraphs (a), (b) or (c) above occurs before employment, during employment or after employment of that person;
- (2) Whether the insured may be liable as an employer or in any other capacity; and
- (3) To any obligation to share damages with or repay someone else who must pay damages because of the injury.

**B. The following exclusion is added to Paragraph 2., Exclusions of Section I – Coverage B – Personal And Advertising Injury Liability:**

This insurance does not apply to:

"Personal and advertising injury" to:

- (1) A person arising out of any:
  - (a) Refusal to employ that person;
  - (b) Termination of that person's employment; or
  - (c) Employment-related practices, policies, acts or omissions, such as coercion, demotion, evaluation, reassignment, discipline, defamation, harassment, humiliation, discrimination or malicious prosecution directed at that person; or
- (2) The spouse, child, parent, brother or sister of that person as a consequence of "personal and advertising injury" to that person at whom any of the employment-related practices described in Paragraphs (a), (b), or (c) above is directed.

This exclusion applies:

- (1) Whether the injury-causing event described in Paragraphs (a), (b) or (c) above occurs before employment, during employment or after employment of that person;
- (2) Whether the insured may be liable as an employer or in any other capacity; and
- (3) To any obligation to share damages with or repay someone else who must pay damages because of the injury.

COMMERCIAL GENERAL LIABILITY  
CG 21 65 12 04

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

**TOTAL POLLUTION EXCLUSION WITH A BUILDING  
HEATING, COOLING AND DEHUMIDIFYING EQUIPMENT  
EXCEPTION AND A HOSTILE FIRE EXCEPTION**

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART

Exclusion f. under Paragraph 2. **Exclusions of Section I – Coverage A – Bodily Injury And Property Damage Liability** is replaced by the following:

This insurance does not apply to:

**f. Pollution**

- (1) "Bodily injury" or "property damage" which would not have occurred in whole or part but for the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of "pollutants" at any time.

This exclusion does not apply to:

- (a) "Bodily injury" if sustained within a building which is or was at any time owned or occupied by, or rented or loaned to, any insured and caused by smoke, fumes, vapor or soot produced by or originating from equipment that is used to heat, cool or dehumidify the building, or equipment that is used to heat water for personal use, by the building's occupants or their guests; or
- (b) "Bodily injury" or "property damage" arising out of heat, smoke or fumes from a "hostile fire" unless that "hostile fire" occurred or originated:
- (i) At any premises, site or location which is or was at any time used by or for any insured or others for the handling, storage, disposal, processing or treatment of waste; or

- (ii) At any premises, site or location on which any insured or any contractors or subcontractors working directly or indirectly on any insured's behalf are performing operations to test for, monitor, clean up, remove, contain, treat, detoxify, neutralize or in any way respond to, or assess the effects of, "pollutants".

- (2) Any loss, cost or expense arising out of any:

- (a) Request, demand, order or statutory or regulatory requirement that any insured or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of, "pollutants"; or
- (b) Claim or suit by or on behalf of a governmental authority for damages because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of, "pollutants".

COMMERCIAL GENERAL LIABILITY  
CG 21 67 12 04

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

## FUNGI OR BACTERIA EXCLUSION

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART

- A. The following exclusion is added to Paragraph 2. Exclusions of Section I – Coverage A – Bodily Injury And Property Damage Liability:

2. Exclusions

This insurance does not apply to:

**Fungi Or Bacteria**

- a. "Bodily injury" or "property damage" which would not have occurred, in whole or in part, but for the actual, alleged or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of, any "fungi" or bacteria on or within a building or structure, including its contents, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such injury or damage.
- b. Any loss, cost or expenses arising out of the abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing, remediating or disposing of, or in any way responding to, or assessing the effects of, "fungi" or bacteria, by any insured or by any other person or entity.

This exclusion does not apply to any "fungi" or bacteria that are, are on, or are contained in, a good or product intended for bodily consumption.

- B. The following exclusion is added to Paragraph 2. Exclusions of Section I – Coverage B – Personal And Advertising Injury Liability:

2. Exclusions

This insurance does not apply to:

**Fungi Or Bacteria**

- a. "Personal and advertising injury" which would not have taken place, in whole or in part, but for the actual, alleged or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of any "fungi" or bacteria on or within a building or structure, including its contents, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such injury.
- b. Any loss, cost or expense arising out of the abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing, remediating or disposing of, or in any way responding to, or assessing the effects of, "fungi" or bacteria, by any insured or by any other person or entity.

- C. The following definition is added to the Definitions Section:

"Fungi" means any type or form of fungus, including mold or mildew and any mycotoxins, spores, scents or byproducts produced or released by fungi.

COMMERCIAL GENERAL LIABILITY  
CG 26 20 10 93

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**NEW JERSEY CHANGES – LOSS INFORMATION**

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART ("OCCURRENCE" VERSION)

The following Condition is added TO COMMERCIAL GENERAL LIABILITY CONDITIONS (Section IV):

**10. Your Right to Loss Information**

We will provide the first Named Insured shown in the Declarations the following loss information relating to this and any preceding general liability Coverage Part we have issued to you during the previous three years:

- a. A list or other record of each "occurrence" of which we were notified in accordance with paragraph 2.a. of the Duties in the Event of Occurrence, Offense, Claim or Suit Condition in this Section. We will include a brief description of the "occurrence" and information on whether any claim arising out of the "occurrence" is open or closed.
- b. A summary by policy year, of payments made and amounts reserved, stated separately under any applicable General Aggregate Limit and Products-Completed Operations Aggregate Limit.

Amounts reserved are based on our judgment. They are subject to change and should not be regarded as ultimate settlement values.

You must not disclose this information to any claimant or any claimant's representative without our consent.

We will provide this information only if we receive a written request from the first Named Insured during the policy period. We will provide this information within 45 days of receipt of the request.

We compile claim and "occurrence" information for our own business purposes and exercise reasonable care in doing so. In providing this information to the first Named Insured, we make no representations or warranties to insureds, insurers or others to whom this information is furnished by or on behalf of any insured.

## **EXHIBIT F**





2017 POLICY

Thank you  
for being  
our policyholder





**POLICYHOLDER DISCLOSURE  
NOTICE OF TERRORISM  
INSURANCE COVERAGE**

Coverage for acts of terrorism is included in your policy. You are hereby notified that under the Terrorism Risk Insurance Act, as amended in 2015, the definition of act of terrorism has changed. As defined in Section 102(1) of the Act: The term "act of terrorism" means any act that is certified by the Secretary of the Treasury—in consultation with the Secretary of Homeland Security, and the Attorney General of the United States—to be an act of terrorism; to be a violent act or an act that is dangerous to human life, property, or infrastructure; to have resulted in damage within the United States, or outside the United States in the case of certain air carriers or vessels or the premises of a United States mission; and to have been committed by an individual or individuals as part of an effort to coerce the civilian population of the United States or to influence the policy or affect the conduct of the United States Government by coercion. Under your coverage, any losses resulting from certified acts of terrorism may be partially reimbursed by the United States Government under a formula established by the Terrorism Risk Insurance Act, as amended. However, your policy may contain other exclusions which might affect your coverage, such as an exclusion for nuclear events. Under the formula, the United States Government generally reimburses 85% through 2015; 84% beginning on January 1, 2016; 83% beginning on January 1, 2017; 82% beginning on January 1, 2018; 81% beginning on January 1, 2019 and 80% beginning on January 1, 2020, of covered terrorism losses exceeding the statutorily established deductible paid by the insurance company providing the coverage. The Terrorism Risk Insurance Act, as amended, contains a \$100 billion cap that limits U.S. Government reimbursement as well as insurers' liability for losses resulting from certified acts of terrorism when the amount of such losses exceeds \$100 billion in any one calendar year. If the aggregate insured losses for all insurers exceed \$100 billion, your coverage may be reduced.

The portion of your annual premium that is attributable to coverage for acts of terrorism is \$0.00, and does not include any charges for the portion of losses covered by the United States government under the Act.

**YOU SHOULD ALSO KNOW THAT UNDER THE TERRORISM RISK INSURANCE ACT, AS AMENDED, ANY LOSSES RESULTING FROM CERTIFIED ACTS OF TERRORISM UNDER YOUR POLICY COVERAGE MAY BE PARTIALLY REIMBURSED BY THE UNITED STATES GOVERNMENT AND MAY BE SUBJECT TO A \$100 BILLION CAP THAT MAY REDUCE YOUR COVERAGE. THE PORTION OF YOUR PREMIUM ATTRIBUTABLE TO SUCH COVERAGE IS SHOWN ABOVE.**

If you have any questions about this notice, please contact your agent or Broker.

NAV-ML-TERRA (02/15)



Commercial Declarations  
NAV-UMB-DEC (4/10)

Policy Number: CH17UMF922034IV  
Producer Number: CONN0358  
New



**Insuring Company:** Navigators Insurance Company  
One Penn Plaza  
New York, NY 10119

**Producer:** Conner Strong & Buckelew  
50 S 16th St  
Philadelphia, PA 19102-2516

**1. Named Insured:** Pernix Therapeutics Holdings Inc  
**Address:** 10 North Park Place, Suite 201  
Morristown, NJ 07960

**Business Type:** Corporation

**2. Policy Period:** From: 11/30/2017 to 11/30/2018  
(At 12:01 a.m. standard time at your mailing address shown above.)

**3. Limits of Insurance**

|                          |             |
|--------------------------|-------------|
| Each Occurrence or Event | \$5,000,000 |
| General Aggregate        | \$5,000,000 |
| Retained Limit           | \$10,000    |

**4. Underlying Insurance:**

See AMENDMENT - SCHEDULE OF UNDERLYING attached

**5. Premium at Inception**

|                    |             |                  |
|--------------------|-------------|------------------|
| Policy Premium:    | \$40,253    |                  |
| Minimum Premium:   | \$40,253    |                  |
| Minimum Earned:    | \$10,063    |                  |
| Terrorism Premium: | \$0         |                  |
| Surcharge:         | \$241.52    | New Jersey PLIGA |
| Total Due:         | \$40,494.52 |                  |

**6. Endorsements Attached to this Policy at Inception**

OPUS Cover Sheet  
POLICYHOLDER DISCLOSURE NOTICE OF TERRORISM  
INSURANCE COVERAGE

OPUS Cover Sheet (02/17)  
NAV-ML-TERRA (02/15)

Commercial Umbrella Liability Declarations  
Commercial Umbrella Liability Coverage Part  
Claim Reporting Procedures  
OFAC ENDORSEMENT  
New Jersey Changes  
CLAIM REPORTING PROCEDURES  
Exclusion - Cyber Injury  
Claims Made Underlying  
Exclusion - Rejected Coverage  
Disclosure Pursuant to Terrorism Risk Insurance Act  
Nuclear Energy Liability Exclusion  
Professional Services Exclusion  
Exclusion - Products-Completed Operations Hazard  
Amendment - Schedule of Underlying  
Cap on Losses from Certified Acts of Terrorism  
Amendment of Dec Named Insured

NAV-UMB-DEC (04/10)  
NAV-UMB-001 (04/10)  
NAV-PHN-200 (06/08)  
NAV-ML-002 (11/12)  
NAV-ECD-200-NJ (04/10)  
NAV-PHN-200 (10/13)  
NAV-UMB-5041 (01/15)  
NAV-UMB-304 (03/10)  
NAV-UMB-321 (08/05)  
IL 09 85 (01/08)  
NAV-UMB-302 (04/05)  
NAV-UMB-305 (03/09)  
NAV-UMB-5024 (05/12)  
NAV-ECD-104 (02/11)  
NAV-ECD-400 (02/15)  
Amendment of Dec Named Insured

Signed at: \_\_\_\_\_

by \_\_\_\_\_

This day of: \_\_\_\_\_

Authorized Representative

## Commercial Umbrella Liability Coverage Part

Various provisions of this policy restrict coverage. Read the entire policy carefully to determine your rights, duties and what is and is not covered.

Throughout the policy the words "you" and "your" refer to the "named insured." The words "we," "us" and "our" refer to the company providing this insurance. The word "insured" means any other person or organization qualifying as such under SECTION II – WHO IS AN INSURED.

Other words and phrases that appear in quotations in this policy have special meanings. Refer to SECTION V - DEFINITIONS.

### SECTION I - COVERAGES

#### 1. Insuring Agreement

##### A. Coverage A – Excess Liability

1. We will pay on behalf of the insured and in excess of "underlying limits" those sums the insured becomes legally obligated to pay as damages for "loss" to which this insurance applies. This insurance applies only if:
  - a. the "loss" is caused by an "event" that takes place in the "coverage territory;"
  - b. the "loss" occurs during the "policy period;" and
  - c. the "scheduled underlying insurance" applies to the "loss."
2. If an aggregate limit of "scheduled underlying insurance" is exhausted by the payment of judgments or settlements to which this insurance applies, or would have applied but for the amount of the damages, this insurance will apply in place of the "scheduled underlying insurance" until we have paid our applicable Limits of Insurance.
3. When paragraph 2. above applies, ending the "scheduled underlying insurance" obligations to investigate and settle claims or defend suits against the insured, we have the right and duty to investigate claims and defend suits which seek damages to which this insurance applies. Our right and duty to defend end when we have paid our applicable Limits of Insurance.
4. When paragraph 2. above does not apply, we have the right, but not the duty, to participate in the investigation or settlement of any claim or the defense of any suit against any insured.
5. We have the right, at our discretion, to settle any claim to which this insurance applies.
6. As respects paragraphs 3. and 4. above, "defense expenses" we incur in the investigation of any claim or defense of any suit will be paid in addition to the Limits of Insurance except when such costs reduce the limits of "scheduled underlying insurance," in which case they will reduce our Limits of Insurance.
7. The amount we pay is limited. See SECTION III – LIMITS OF INSURANCE.

**B. Coverage B – Umbrella Liability**

1. When Coverage A – Excess Liability does not apply, we will pay on your behalf and in excess of the "retained limit," those sums you become legally obligated to pay as damages because of "bodily injury" or "property damage" to which this insurance applies. This insurance applies only if the "bodily injury" or "property damage:"
  - a. is caused by an "occurrence" in the "coverage territory;" and
  - b. occurs during the "policy period," whether or not such "bodily injury" or "property damage" continues, progresses, changes or resumes after the "policy period."
2. We have the right and duty to investigate claims and defend "suits" against you which seek damages to which this insurance applies when no other carrier is obligated to investigate or defend. Our right and duty to defend end when we have paid our applicable Limits of Insurance.
3. We have the right, at our discretion, to settle any claim to which this insurance applies. If, when settling a claim, we pay amounts within the "retained limit," you will promptly reimburse us for those amounts.
4. Any "defense expenses" we incur in the investigation of any claim or defense of any "suit" will be paid in addition to our Limits of Insurance.
5. The amount we pay is limited. See SECTION III – LIMITS OF INSURANCE.

**2. Exclusions**

The EXCLUSIONS sections of the "scheduled underlying insurance" are made part of this policy and apply to Coverage A – Excess Liability and Coverage B – Umbrella Liability. If an inconsistency or contradiction exists between an Exclusion of this policy and an Exclusion of the "scheduled underlying insurance" the Exclusion of this policy will apply.

**A. Under Coverage B – Umbrella Liability, this insurance does not apply to:**

1. any liability to which Coverage A – Excess Liability or "scheduled underlying insurance:"
  - a. applies; or
  - b. would apply but for:
    - i. an exclusion in this policy or the "scheduled underlying insurance;"
    - ii. the exhaustion or erosion of an aggregate limit of insurance; or
    - iii. any failure to maintain "scheduled underlying insurance" in accordance with SECTION IV – CONDITIONS, 8. Maintenance of Scheduled Underlying Insurance;
2. any liability arising out of the ownership, maintenance, operation or use of any:
  - a. aircraft;
  - b. watercraft greater than 51 feet in length; or
  - c. watercraft used to carry passengers or property for a charge;
3. "bodily injury" to:
  - a. any "employee" of any insured arising out of and in the course of:
    - i. employment by any insured; or

- ii. performing duties related to the conduct of any insured's business; or
  - b. the spouse, child, parent, relative, brother or sister of that "employee" as a consequence of paragraph 3. a. above;
- 4. any liability arising out of the ownership, maintenance, operation or use, including loading or unloading, of an "automobile." This exclusion does not apply to an "automobile" you own while operated outside of the United States of America, its territories, possessions or Canada;
- 5. any liability assumed in any contract or agreement;
- 6. any liability arising out of the actual, alleged, suspected or threatened discharge, dispersal, seepage, migration, escape or release of "pollutants;"
- 7. any liability arising out of the rendering or failure to render any "professional services;"
- 8. any liability arising out of any act of terrorism.
- B. Under Coverage A – Excess Liability and Coverage B – Umbrella Liability, this insurance does not apply to any liability:
  - 1. for which coverage is excluded by the "scheduled underlying insurance;"
  - 2. for which coverage is provided by "scheduled underlying insurance" at limits less than the limits of insurance applicable to other coverage provided by the "scheduled underlying insurance" and less than "underlying limits;"
  - 3. for "bodily injury," "loss" or "property damage" which commenced prior to this "policy period," whether or not such "bodily injury," "loss" or "property damage" continues, progresses, changes or resumes during this "policy period;"
  - 4. for damage to property you own, rent or occupy, including any costs or expenses incurred by you or any other person, organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including the prevention of injury to a person or damage to another's property;
  - 5. for damage to personal property in the care, custody or control of any insured;
  - 6. arising out of any "aircraft products;"
  - 7. arising out of the actual, alleged, suspected or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of "asbestos;"
  - 8. arising out of the actual, alleged, suspected or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of "fungi" or bacteria;
  - 9. arising out of the actual, alleged, suspected or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of "silica" or "silica related dust;"
  - 10. arising out of any "employment practices" of any insured;
  - 11. arising out of:
    - a. war, including undeclared or civil war;
    - b. warlike action by a military force, including action in hindering or defending against an actual or expected attack, by any government, sovereign or other authority using military personnel or other agents; or

- c. insurrection, rebellion, revolution, usurped power, or action taken by governmental authority in hindering or defending against any of these;
12. imposed under:
- a. an uninsured or underinsured motorist, uninsured or underinsured boater, Medical Payments, Personal Injury Protection, No-Fault or any similar law;
  - b. a workers compensation, disability benefits, unemployment compensation or any similar law;
  - c. the Employee Retirement Income Security Act of 1974, any amendments thereto or any similar law.

## SECTION II – WHO IS AN INSURED

1. Under Coverage A – Excess Liability, the "named insured" is an insured, and any other person or organization who qualifies as an insured under "scheduled underlying insurance" is an insured, however, coverage provided such insureds will not be broader than coverage provided by "scheduled underlying insurance."
2. Under Coverage B - Umbrella Liability, the "named insured" is the only insured.

## SECTION III – LIMITS OF INSURANCE

The Limits of Insurance shown in the Declarations and the rules below fix the most we will pay regardless of the number of insureds, claims made or "suits" brought, or persons or organizations making claims or bringing "suits."

### 1. Coverage A – Excess Liability

- A. The General Aggregate Limit is the most we will pay for the sum of all damages to which this Coverage applies, except:
  1. damages because of bodily injury or property damage included within the "products-completed operations hazard;" or
  2. damages arising out of the ownership, operation, maintenance or use of an "automobile;"

When "scheduled underlying insurance" has a General Aggregate Limit which applies separately and fully to each of your projects or each of your locations, this General Aggregate will apply in the same manner.

- B. The Products-Completed Operations Aggregate Limit is the most we will pay for the sum of all damages included within the "products-completed operations hazard;"
- C. Subject to paragraphs 1. A. and 1. B. above, the Each Occurrence Limit is the most we will pay for the sum of all damages that arise out of any one "event."

### 2. Coverage B – Umbrella Liability

- A. The General Aggregate Limit is the most we will pay for the sum of all damages to which this Coverage applies;

- B. Subject to paragraph 2. A. above, the Each Occurrence Limit is the most we will pay for the sum of all damages that arise out of any one "occurrence."

#### SECTION IV – CONDITIONS

The CONDITIONS sections of the "scheduled underlying insurance" are made part of this policy and apply to Coverage A – Excess Liability and Coverage B – Umbrella Liability. If an inconsistency or contradiction exists between the Conditions of this policy and the Conditions of the "scheduled underlying insurance," the Conditions of this policy will apply.

1. Appeals

At our discretion we may appeal any judgment which would result in a payment under this policy. When we do appeal, we will pay all costs associated with the appeal in addition to the Limits of Insurance. Any such appeal will not increase our Limits of Insurance.

2. Bankruptcy or Insolvency

Bankruptcy or insolvency of the insured or the insured's estate will not relieve us of our obligations under this policy. Bankruptcy or insolvency of any company providing "scheduled underlying insurance" will not reduce the "underlying limits" or increase our obligations under this policy. We will not be required to drop down or replace "scheduled underlying insurance."

3. Cancellation

- a. The "first named insured" may cancel this policy at any time by providing us advanced written notice of the cancellation date.
- b. We may cancel this policy at any time by providing the "first named insured" written notice of cancellation:
  - i. at least 10 days in advance if we cancel for non-payment of premium; or
  - ii. at least 30 days in advance if we cancel for any other reason.
 Return premium, if any, will be calculated per Condition 11. Premium. Proof of mailing will be proof of notice.

4. Non-Renewal

- a. We are not obligated to renew this policy. However, should we decide not to renew, we will provide the "first named insured" written notice of our decision at least 30 days prior to the expiration date shown in the Declarations.
- b. We will not restrict the terms or increase premium of this policy at renewal unless we have given the "first named insured" at least 30 days advanced notice of any such changes. However, no notice will be provided or required if a restriction in this policy results from a restriction applicable to "scheduled underlying insurance."
- c. The "first named insured" may non-renew this policy by:
  - i. providing advance written notice to us;
  - ii. rejecting our offer to renew; or
  - iii. failing to reply to our offer to renew.
 Proof of mailing will be proof of notice.

5. Changes

This policy contains all of the agreements between you and us. This policy may only be



changed by endorsements we issue.

6. Duties When There is an "Event," "Occurrence," Claim or "Suit"

- a. You must see to it that we, and any other insurers who could provide coverage, are notified as soon as practicable of any "event" or "occurrence" which may be reasonably expected to result in a claim under this policy. To the extent possible, notice should include:
    - i. how, when and where the "event" or "occurrence" took place;
    - ii. the names and addresses of any injured persons and witnesses; and
    - iii. the nature and location of any injury or damage arising out of the "event" or "occurrence."
  - b. If a claim is made or "suit" is brought against any insured which may be reasonably expected to result in a claim under this policy, you must:
    - i. immediately record the specifics of the claim or "suit" and the date received; and
    - ii. notify us, and any other insurers who could provide coverage, as soon as practicable.
  - c. You and any other involved insured must:
    - i. immediately send us, and any other insurers who could provide coverage, copies of any demands, notices, summonses or legal papers received in connection with a claim or "suit" which may be reasonably expected to result in a claim under this policy;
    - ii. authorize us to obtain records and other information;
    - iii. cooperate with us in the investigation or settlement of the claim, issues relating to coverage under this policy or defense against the "suit;" and
    - iv. assist us, upon our request, in the enforcement of any right against any person or organization which may be liable to the insured because of the injury or damage to which this insurance may apply.
  - d. No insured will, except at that insured's own cost, voluntarily make a payment, assume any obligation or incur any expense, other than first aid, without our consent.
- Notice to us may be sent to our address shown in the Declarations.

7. Legal Action Against Us

No person or organization has a right under this insurance:

- a. to join us as a party or otherwise bring us into a "suit" asking for damages from an insured; or
- b. to sue us on this insurance unless all of its terms have been fully complied with.

8. Maintenance of Scheduled Underlying Insurance

During the "policy period" you must maintain "scheduled underlying insurance" with "underlying limits" at least equal to the amounts shown in the Declarations. The "underlying limits" must be unimpaired at the beginning of this "policy period."

If you fail to comply with this condition, we will only be liable to the extent we would have been liable had you complied. Reduction of "underlying limits" by the payment of judgments or settlements for "loss" to which this insurance applies, or would have applied but for the amount of the damages, will not be considered a failure to maintain "underlying limits."



9. **Other Insurance**  
This insurance is excess over any insurance available to the insured except insurance purchased specifically to apply in excess of this policy.
10. **Payment of Damages**  
When the amount of damages payable under this policy has been determined by final judgment or a written settlement agreement between the claimant and us, we will pay that amount, up to our applicable Limits of Insurance, after the "scheduled underlying insurance" or the insured has paid the full amount of the "underlying limits" or, if it applies, the "retained limit."
11. **Premium**  
The Premium shown in the Declarations is the premium for the coverage we provide for the "policy period." The "first named insured" is responsible for the payment of all premiums under this policy. If this policy is cancelled prior to its expiration date return premium will be calculated as follows:
  - a. if cancelled by us:  

$$(((\text{Premium}) - (\text{Minimum Earned Premium})) \times (\text{Pro Rata factor}))$$
  - b. if cancelled by you:  

$$(((\text{Premium}) - (\text{Minimum Earned Premium})) \times ((\text{Pro Rata factor}) \times (.90)))$$
12. **Separation of Insureds**  
Except with respect to the Limits of Insurance and any rights or duties specifically assigned in this policy to the "first named insured," this insurance applies:
  - a. as if each "named insured" were the only "named insured;" and
  - b. separately to each insured against whom claim is made or "suit" is brought.
13. **Transfer of Rights of Recovery Against Others**  
If an insured has rights to recover all or part of any payment we have made under this insurance, the insured must preserve those rights and, at our request, pursue or transfer those rights to us. The insured must do nothing after an "event" or "occurrence" to impair them.
14. **Reformation of Underlying**  
If the "scheduled underlying insurance" is reformed after an "event" to provide coverage for a "loss," the terms of such reformation do not apply to this policy.
15. **When we Defend**  
When we have a duty to defend an insured under Coverage A – Excess Liability, the insured will cooperate with us in the transfer of the defense to counsel of our choosing. When we have a duty to defend you under Coverage B – Umbrella Liability, we have the right to select counsel.  
If the law of the governing jurisdiction permits you to select your own counsel to be paid for by us, we shall only be liable for the reasonable and necessary defense costs of one law firm per "named insured" at rates customarily paid by us for the defense of similar claims in the jurisdiction where the claim is pending.
16. **Claims outside the U.S.A, it's Territories, Possessions or Canada**  
When we have the duty to defend an insured and are prevented by law or otherwise from

doing so, we will reimburse the insured for any reasonable and necessary expenses incurred in the defense of a "suit" to which this insurance applies.

If the insured becomes legally obligated to pay damages to which this insurance applies and we are prevented by law from paying such damages on behalf of the insured, we will reimburse the insured, in U.S. currency at the prevailing exchange rate at the time the damages were paid, for such damages.

#### SECTION V – DEFINITIONS

The DEFINITIONS sections of the "scheduled underlying insurance" are made part of this policy, and apply to words or phrases used in this policy, provided always that words or phrases in quotations in this policy will have the meaning given them in this policy.

"Aircraft products" means:

- a. an aircraft;
- b. ground control or support equipment; or
- c. any article, component or device made, sold, licensed, handled or distributed by any insured that is used to achieve, control or maintain flight or landing of an aircraft.

"Asbestos" means the mineral in any form.

"Automobile" means a land motor vehicle, trailer or semi-trailer designed principally for travel on public roads, including any attached machinery or equipment. But "automobile" does not include mobile equipment.

"Bodily Injury" means bodily injury, sickness or disease sustained by a person, including mental injury, mental anguish or death resulting from any of these.

"Coverage territory" means anywhere in the world with the exception of any country or jurisdiction which is subject to trade or other economic sanctions or embargo by the United States of America.

"Defense expenses" means expenses we incur to investigate a claim or defend a "suit." Defense expenses include interest which accrues on our portion of a judgment, after entry of that judgment and after the insured or any underlying insurer has paid the full amount of their portion of the judgment but before we have paid, offered to pay or deposited in the court the part of the judgment that is within our applicable Limits of Insurance.

"Electronic data" means information, facts or programs stored as or on, created or used on, or transmitted to or from computer software, including systems and applications software, hard or floppy disks, CD-ROMS, tapes, drives, cells, data processing devices or any other media which are used with electronically controlled equipment.

"Employment practices" means:

- a. dismissal, discharge or termination of employment, whether actual, constructive or retaliatory;
- b. failure or refusal to hire or promote;
- c. discipline, demotion, coercion or retaliatory treatment;

- d. failure to grant tenure;
- e. negligent employment evaluation;
- f. sexual or other workplace harassment, including quid pro quo and hostile work environment;
- g. employment discrimination;
- h. invasion of privacy, violation of employment related civil rights, employment related libel, slander or defamation;
- i. creating or enforcing or failing to create or enforce employment related policies or procedures; or
- j. actual or alleged violations of the Family and Medical Leave Act of 1993 or its amendments.

"Employee" means any person employed by an insured. Employee includes a person leased to an insured by an employee-leasing firm.

"Event" means an accident, incident, occurrence, offense, wrongful act or other "loss" causing event defined by and to which the "scheduled underlying insurance" applies.

"First named insured" means the "named insured" listed first in the Declarations of this policy.

"Fungi" means any type or form of fungus, including mold or mildew and any mycotoxins, spores, scents or byproducts produced or released by fungi. But "fungi" does not include mushrooms cultivated for human consumption.

"Loss" means bodily injury, property damage, personal and advertising injury or other loss defined by and to which the "scheduled underlying insurance" applies.

"Named insured" means the person or organization shown in the Declarations of this policy and, if you are designated in the Declarations as:

- a. an individual, you and your spouse or domestic partner, but only as respects the conduct of the business of which you are the sole proprietor;
- b. a partnership or joint venture, you and your partners or members and their spouses or domestic partners, but only as respects the conduct of the business of the partnership or joint venture;
- c. a Limited Liability Company, you and your members, but only as respects the conduct of the business of your Limited Liability Company;
- d. a trust, you and your trustees are insureds, but only with respect to the conduct of the business of the trust;
- e. any other organization, you and your officers and directors, but only with respect to their duties as officers and directors, and your stockholders, but only with respect to their liability as stockholders.

However, no person or organization is a "named insured" with respect to the conduct of a partnership, joint venture or Limited Liability Company that is not shown as a "named insured" in the Declarations of this policy.

"Occurrence" means an accident, including continuous or repeated exposure to substantially the

same general harmful conditions.

"Policy period" means the period of time between the effective date shown in the Declarations and the earlier of the expiration date shown in the Declarations or the expiration date shown in an endorsement to this policy.

"Pollutants" mean any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled or reclaimed.

"Products-completed operations hazard:"

- a. Includes all bodily injury and property damage occurring away from premises you own or rent and arising out of "your product" or "your work" except:
  1. products that are still in your physical possession; or
  2. work that has not yet been completed or abandoned. However, your work will be deemed completed at the earliest of the following times:
    - i. when all of the work called for in your contract has been completed;
    - ii. when all of the work to be done at the job site has been completed if your contract calls for work at more than one job site;
    - iii. when that part of the work done at the job site has been put to its intended use by any person or organization other than another contractor or subcontractor working on the same project.

Work that may need service, maintenance, correction, repair or replacement, but which is otherwise complete, will be treated as completed.
- b. Does not include bodily injury or property damage arising out of:
  1. the transportation of property, unless the injury or damage arises out of a condition in or on a vehicle not owned or operated by you, and that condition was created by the loading or unloading of that vehicle by any insured; or
  2. the existence of tools, uninstalled equipment or abandoned or unused material.

"Professional services" includes but is not limited to:

- a. real estate, travel, legal, accounting or advertising services;
- b. preparing, approving, or failing to prepare or approve maps, shop drawings, opinions, reports, surveys, field orders, change orders, designs, drawings or specifications;
- c. engineering, architectural or surveying services, including related supervisory or inspection services;
- d. medical, surgical, dental, x-ray or nursing services treatment, advice or instruction;
- e. any health, physical fitness, dietary, rehabilitative or therapeutic service treatment, advice or instruction;
- f. any service, treatment, advice or instruction for the purpose of appearance or skin enhancement, hair removal or replacement or personal grooming;
- g. optometry or optical or hearing aid services including the prescribing, preparation, fitting, demonstration or distribution of ophthalmic lenses or similar products or hearing aid devices;

- i. body piercing or tattooing services;
- i. services in the practice of pharmacy;
- j. services, collection or distribution of blood or blood products;
- k. law enforcement or firefighting services; and
- l. handling, embalming, disposal, burial, cremation, interment or disinterment of dead bodies.

"Property damage" means:

- a. physical injury to tangible property, including all resulting loss of use of that property. All such loss of use shall be deemed to occur at the time of the physical injury that caused it; or
- b. loss of use of tangible property that is not physically injured. All such loss of use shall be deemed to occur at the time of the "occurrence" that caused it.

For the purposes of this insurance, "electronic data" is not tangible property.

"Retained limit" means the amount, shown in the Declarations, which you must pay for each claim when Coverage B – Umbrella Liability applies.

"Scheduled underlying insurance" means the insurance policy, listed in the Schedule of Underlying Insurance in the Declarations, or its renewal or replacement, which applies to the "loss," or would have applied but for:

- a. an exclusion in the "scheduled underlying insurance;"
- b. the exhaustion or erosion of an aggregate limit of insurance; or
- c. any failure to maintain "scheduled underlying insurance" in accordance with SECTION IV – CONDITIONS, 8. Maintenance of Scheduled Underlying Insurance.

If more than one policy is listed in the Schedule, the "scheduled underlying insurance" is the policy which applies to the "loss" or would have applied to the "loss" but for the reasons a., b., c., listed above.

"Silica" means silicon dioxide occurring in crystalline, amorphous or impure forms, silica particles, silica dust or silica compounds.

"Silica related dust" means a mixture or combination of silica and other dust particles.

"Suit" means a civil proceeding in which damages, to which this insurance applies, are alleged.

"Suit" includes:

- a. an arbitration proceeding in which such damages are claimed and to which the insured must submit or does submit with our consent; or
- b. any other alternative dispute resolution proceeding in which such damages are claimed and to which the insured submits with our consent.

"Underlying limits" means the amounts shown in the Declarations as the minimum limits of insurance to be provided by "scheduled underlying insurance."

"Your products" means:

- a. any goods or products, other than real property, manufactured, sold, handled, licensed, distributed or disposed of by:

- i. you;
- ii. others trading under your name; or
- iii. a person or organization whose business or assets you have acquired; and
- b. containers, other than vehicles, materials, parts or equipment furnished in connection with such goods or products.

"Your product" includes:

- c. warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of "your product;" and
- d. the providing of or failure to provide warnings or instructions.

"Your product" does not include vending machines or other property rented to or located for the use of others but not sold.

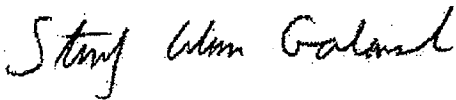
"Your work" means:

- a. work or operations performed by you or on your behalf; and
- b. materials, parts or equipment furnished in connection with such work or operations.

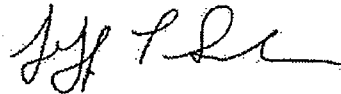
"Your work" includes:

- c. warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of "your work;" and
- d. the providing of or failure to provide warnings or instructions.

In Witness Whereof, the issuing Company has caused this policy to be signed officially below, and countersigned on the Declarations page by a duly authorized representative of said Company.



Stanley A. Gafanski  
President



Jeff L. Saunders  
Vice President

## Policyholder Notice



### CLAIM REPORTING PROCEDURES

Conditions of the policy require that in the event of a claim, you notify us as soon as practicable. All claims notifications are to be reported to the Rye Brook Claims Office by electronic mail to [RBClaims@navg.com](mailto:RBClaims@navg.com).

In the alternative, claim notices may also be:

- mailed to the Rye Brook Claims Office at:

Navigators Management Co., Inc.  
Claims Division  
6 International Drive, Suite 100  
Rye Brook, NY 10573

- or faxed to 914-933-6018

All claims notifications must be accompanied by an ACORD loss form and should contain current contact information for the insured and claimant(s) as well as detailed description of the loss.

If the insured files a claim with the agent, it is the agent's responsibility to forward the claim to the Rye Brook Claim Office.

## **OFAC ENDORSEMENT**

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

### **U.S. ECONOMIC AND TRADE SANCTIONS LIMITATIONS CLAUSE**

No insurer shall be deemed to provide cover and no insurer shall be liable to pay any claim or provide any benefit hereunder to the extent that the provision of such cover, payment of such claim or provision of such benefit would expose that insurer to any sanction, prohibition or restriction under the trade or economic sanctions, laws or regulations of the United States of America.

The United States of America trade or economic sanctions, laws or regulations shall include, but not be limited to, those sanctions administered and enforced by the U.S. Treasury Department's Office of Foreign Assets Control (OFAC).

All other terms, conditions and exclusions of this Policy remain unchanged.



**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**NEW JERSEY CHANGES**

The following applies and supersedes any other provision to the contrary:

- A. Pursuant to New Jersey law, this policy cannot be cancelled or nonrenewed for any underwriting reason or guideline which is arbitrary, capricious or unfairly discriminatory or without adequate prior notice to the insured. The underwriting reasons or guidelines that an insurer can use to cancel or nonrenew this policy are maintained by the insurer in writing and will be furnished to the insured and/or the insured's lawful representative upon written request.

This provision shall not apply to any policy which has been in effect for less than 60 days at the time notice of cancellation is mailed or delivered, unless the policy is a renewal policy.

B. Cancellation:

1. If this policy has been in effect for less than 60 days, we may cancel this policy for any reason subject to the following:
  - a. We may cancel this policy by mailing or delivering to you, and any person entitled to notice under this policy, written notice of cancellation at least:
    - (1) 10 days before the effective date of cancellation if we cancel for:
      - (a) Nonpayment of premium; or
      - (b) Existence of a moral hazard, as defined in N.J.A.C. 11:1-20.2(f) as follows:
        - (i) "The risk, danger or probability that the insured will destroy, or permit to be destroyed, the insured property for the purpose of collecting the insurance proceeds. Any change in the circumstances of an insured that will increase the probability of such a destruction may be considered a 'moral hazard'; and
        - (ii) "The substantial risk, danger or probability that the character, circumstances or personal habits of the insured may increase the possibility of loss or liability for which an insurer will be held responsible. Any change in the character or circumstances of an individual, corporate, partnership or other insured that will increase the probability of such a loss or liability may be considered a 'moral hazard'".
    - (2) 30 days before the effective date of cancellation if we cancel for any other reason.

In the notice of cancellation we will state the reason for cancellation.

2. If this policy has been in effect for 60 days or more, or is a renewal of a policy we issued, we may cancel this policy only for one or more of the following reasons:
  - a. Nonpayment of premium;
  - b. Existence of a moral hazard, as defined in N.J.A.C. 11:1-20.2(f);
  - c. Material misrepresentation or nondisclosure to us of a material fact at the time of acceptance of the risk;
  - d. Increased hazard or material change in the risk assumed which we could not have reasonably contemplated at the time of assumption of the risk;
  - e. Substantial breaches of contractual duties, conditions or warranties that materially affect the nature and/or insurability of the risk;
  - f. Lack of cooperation from the insured on loss control matters materially affecting insurability of the risk;

- g. Fraudulent acts against us by the insured or its representative that materially affect the nature of the risk insured;
  - h. Loss of or reduction in available insurance capacity;
  - i. Material increase in exposure arising out of changes in statutory or case law subsequent to the issuance of the insurance contract or any subsequent renewal;
  - j. Loss of or substantial changes in applicable reinsurance;
  - k. Failure by the insured to comply with any Federal, State or local fire, health, safety or building or construction regulation, law or ordinance with respect to an insured risk which substantially increases any hazard insured against within 60 days of written notification of a violation of any such law, regulation or ordinance;
  - l. Failure by the insured to provide reasonable and necessary underwriting information to us upon written request therefore and a reasonable opportunity to respond;
  - m. Agency termination, provided:
    - (1) We document that replacement coverage at comparable rates and terms has been provided to you, and we have informed you, in writing, of the right to continue coverage with us; or
    - (2) We have informed you, in writing, of the right to continue coverage with us and you have agreed, in writing, to the cancellation or nonrenewal based on the termination of the your appointed agent.
  - n. Any other reasons in accordance with our underwriting guidelines for cancellation of commercial lines coverage.
3. If we cancel this policy based on Paragraphs 2.a. or 2.b. above, we will mail or deliver a written notice, to you and any person entitled to notice under this policy, at least 10 days before the effective date of cancellation. If we cancel this policy for any other reason listed above, we will mail or deliver a written notice to you and any person entitled to notice under this policy, not more than 120 days nor less than 30 days before the effective date of such cancellation.
  4. In the notice of cancellation which is sent to you, we will state the reason for cancellation. For cancellation due to the nonpayment of premium, the notice will state the effect of nonpayment by the due date. Cancellation for nonpayment of premium will not be effective if payment of the amount due is made before the effective date set forth in the notice.
  5. Notice will be sent to the last mailing addresses known to us, by:
    - a. Certified mail; or
    - b. First class mail, if we have obtained from the post office a date stamped proof of mailing showing names and addresses.
  6. We need not send notice of cancellation if you have:
    - a. Replaced coverage elsewhere; or
    - b. Specifically requested termination.
- C. Non-Renewal:
1. We may elect not to renew this policy for any reason permitted to cancel it. If we elect not to renew this policy, we will mail a notice of nonrenewal, stating the reasons for nonrenewal, you at least 30 days but not more than 120 days before the expiration date of this policy. If this policy does not have a fixed expiration date, it shall be deemed to expire annually on the anniversary of its inception.
  2. This notice will be sent to you at the last mailing address known to us by:
    - a. Certified mail; or
    - b. First class mail, if we have obtained from the post office a date stamped proof of mailing showing your name and address.
  3. We need not mail or deliver this notice if you have:
    - a. Replaced coverage elsewhere; or
    - b. Specifically requested termination.

All other terms of the policy remain unchanged.

## Policyholder Notice

### CLAIM REPORTING PROCEDURES

Conditions of the policy require that in the event of a claim, you notify us as soon as practicable. All claim notifications are to be reported to the Schaumburg Claims Office by electronic mail to [RBCclaims@navg.com](mailto:RBCclaims@navg.com).

In the alternative, claim notices may also be:

- Mailed to the Schaumburg Claims Office at:

Navigators Management Co., Inc.  
Claims Division  
1375 E. Woodfield Road, Suite 720  
Schaumburg, IL 60173

- Or faxed to 203-658-1824
- Or telephone 855-444-4796

All claims notifications must be accompanied by an ACORD loss form and should contain current contact information for the insured and claimant(s) as well as a detailed description of the loss.

If the insured files a claim with the agent, it is the agent's responsibility to forward the claim to the Schaumburg Claims Office.

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

## **EXCLUSION – CYBER INJURY**

A. The following is added to SECTION I – COVERAGES, 2. Exclusions, B. Under Coverage A – Excess Liability and Coverage B – Umbrella Liability, this insurance does not apply to any liability:

1. arising out of "cyber injury;" or
2. any loss, cost or expense arising out of any:
  - a. request, demand, order or statutory or regulatory requirement that any insured or others monitor, notify or in any way respond to an actual or alleged "cyber injury;"
  - b. claim or suit by or on behalf of a governmental authority for damages because of monitoring, notifying or in any way responding to a "cyber injury;"

incurred by you or others.

B. The following are added to SECTION V – DEFINITIONS:

1. "Cyber injury" means any actual or suspected, intentional or unintentional breach of any data, software or hardware, wherever located, that results in:
  - a. loss; destruction; disclosure; disruption; inspection; modification; recording; release; review; or use of "personal information;"
  - b. inability to access any website or any electronic system;
  - c. release, introduction or facilitation of any "malicious code;"
  - d. forensic or investigative expenses;
  - e. extortion or terrorism acts or threats;
  - f. monitoring or notification costs or expenses;
  - g. crisis management or public relations expenses;
  - h. data or system recovery, repair, replacement or restoration expenses; or
  - i. business interruption expenses.
2. "Malicious code" includes, but is not limited to any virus, Trojan horse, worm, spyware, logic bomb, adware, malware or other similar software program.
3. "Personal information" means any personal, or personally, identifiable, or identifying, information, as defined by federal, state or local laws, statutes or regulations.

All other terms and conditions of the policy remain unchanged.

**COMMERCIAL UMBRELLA LIABILITY**

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**CLAIMS MADE UNDERLYING**

This endorsement modifies insurance provided under the following:

**COMMERCIAL UMBRELLA LIABILITY COVERAGE PART**

When "scheduled underlying insurance" applies on a Claims-Made basis, this insurance will apply on a Claims-Made basis and the following changes apply:

- A. SECTION I - COVERAGES, 1. Insuring Agreement, Coverage A. - Excess Liability, paragraph 1. is deleted and replaced by the following:

1. We will pay on behalf of the insured and in excess of "underlying limits" those sums the insured becomes legally obligated to pay as damages for "loss" to which this insurance applies. This insurance applies only if:
  - a. the "loss" is caused by an "event" that takes place in the "coverage territory;"
  - b. the "loss" did not occur before the Retroactive Date, shown in paragraph D of this endorsement or after the end of the "policy period;"
  - c. the "scheduled underlying insurance" applies to the "loss;" and
  - d. a claim for damages because of the "loss" is first made against the insured and reported to us during the "policy period" or any applicable Extended Reporting Period we provide.

- B. The following is added to SECTION I - COVERAGES, 1. Insuring Agreement, Coverage A. - Excess Liability:

All claims for damages because of "loss" to the same person will be deemed to have been made at the time the first of those claims is made against any insured.

- C. As respects the coverage provided by this endorsement, SECTION I - COVERAGES, 2. Exclusions, B. 3. is deleted and replaced by the following:

3. for "loss" which commenced prior to the Retroactive Date shown in paragraph D below, whether or not such "loss" continues, progresses, changes, or resumes during this "policy period."

## D. Retroactive Date:

| Carrier                      | Policy Number   | Coverage                    | Retro Date |
|------------------------------|-----------------|-----------------------------|------------|
| Navigators Insurance Company | CH17NCP02048000 | Employee Benefits Liability | 10/01/2014 |

If no date is shown, the Retroactive Date will be the effective date shown in the Declarations of this policy.

## E. Extended Reporting Periods

An Extended Reporting Period provides additional time, after the end of the "policy period," during which you may continue to report claims to us. An Extended Reporting Period does not change the "policy period," increase limits of insurance or reinstate any aggregate limit.

When a Basic Extended Reporting Period applies to the "scheduled underlying insurance" without a premium charge, a Basic Extended Reporting Period will also apply to this policy for the period provided by the "scheduled underlying insurance;" but not more than 30 days after the end of this "policy period."

When a Supplemental Extended Reporting Period applies to the "scheduled underlying insurance" for an additional premium charge, a Supplemental Extended Reporting Period may, for an additional premium, also apply to this policy, provided that you request that we provide a Supplemental Extended Reporting Period and promptly pay any premium due. The Supplemental Extended Reporting Period will terminate on \_\_\_/\_\_\_/\_\_\_ or, if no date is shown here, the termination date of the Supplemental Extended Reporting Period of the "scheduled underlying insurances;" but not more than two years from the end of this "policy period."

Premium for a Supplemental Extended Reporting Period will not exceed 200% of the policy premium. Once the premium has been paid, the Supplemental Extended Reporting Period cannot be cancelled, and the premium cannot be refunded.

If this policy is cancelled for nonpayment of premium prior to the end of the "policy period" no Basic Extended Reporting Period will apply and no Supplemental Extended Reporting Period may be purchased.

All other terms of the policy remain unchanged.

**COMMERCIAL UMBRELLA LIABILITY**

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**EXCLUSION - REJECTED COVERAGE**

This endorsement modifies insurance provided under the following:

**COMMERCIAL UMBRELLA LIABILITY COVERAGE PART**

- A. SECTION I - COVERAGES, 2. Exclusions, A. 8, is deleted and replaced by the following:
- 8. any liability for which coverage was available on the "scheduled underlying insurance" but which you did not purchase.

All other terms of the policy remain unchanged.

POLICY NUMBER: CH17UMF922034IV

IL 09 85 01 08

**THIS ENDORSEMENT IS ATTACHED TO AND MADE PART OF YOUR POLICY IN RESPONSE TO THE DISCLOSURE REQUIREMENTS OF THE TERRORISM RISK INSURANCE ACT. THIS ENDORSEMENT DOES NOT GRANT ANY COVERAGE OR CHANGE THE TERMS AND CONDITIONS OF ANY COVERAGE UNDER THE POLICY.**

## **DISCLOSURE PURSUANT TO TERRORISM RISK INSURANCE ACT**

### **SCHEDULE**

**Terrorism Premium (Certified Acts) "SEE DECLARATIONS"**

**This premium is the total Certified Acts premium attributable to the following Coverage Part(s), Coverage Form(s) and/or Policy(s):**

**Additional information, if any, concerning the terrorism premium:**

**Information required to complete this Schedule, if not shown above, will be shown in the Declarations.**

**A. Disclosure Of Premium**

In accordance with the federal Terrorism Risk Insurance Act, we are required to provide you with a notice disclosing the portion of your premium, if any, attributable to coverage for terrorist acts certified under the Terrorism Risk Insurance Act. The portion of your premium attributable to such coverage is shown in the Schedule of this endorsement or in the policy Declarations.

**B. Disclosure Of Federal Participation In Payment Of Terrorism Losses**

The United States Government, Department of the Treasury, will pay a share of terrorism losses insured under the federal program. The federal share equals 85% of that portion of the amount of such insured losses that exceeds the applicable insurer retention. However, if aggregate insured losses attributable to terrorist acts certified under the Terrorism Risk Insurance Act exceed \$100 billion in a Program Year (January 1 through December 31), the Treasury shall not make any payment for any portion of the amount of such losses that exceeds \$100 billion.

**C. Cap On Insurer Participation In Payment Of Terrorism Losses**

If aggregate insured losses attributable to terrorist acts certified under the Terrorism Risk Insurance Act exceed \$100 billion in a Program Year (January 1 through December 31) and we have met our insurer deductible under the Terrorism Risk Insurance Act, we shall not be liable for the payment of any portion of the amount of such losses that exceeds \$100 billion, and in such case insured losses up to that amount are subject to pro rata allocation in accordance with procedures established by the Secretary of the Treasury.



**COMMERCIAL UMBRELLA LIABILITY**

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**NUCLEAR ENERGY LIABILITY EXCLUSION**

This endorsement modifies insurance provided under the following:

**COMMERCIAL UMBRELLA LIABILITY COVERAGE PART**

The following is added to SECTION I - COVERAGES, 2. Exclusions, B:

This insurance does not apply:

1. to any liability:
  - a. with respect to which an insured under the policy is also an insured under a nuclear energy liability policy issued by Nuclear Energy Liability Insurance Association, Mutual Atomic Energy Liability Underwriters or Nuclear Insurance Association of Canada, or would be an insured under any such policy but for its termination upon exhaustion of its limit of liability; or
  - b. resulting from the hazardous properties of nuclear material and with respect to which:
    - i. any person or organization is required to maintain financial protection pursuant to the Atomic Energy Act of 1954, or any law amendatory thereof; or
    - ii. the insured is, or had this policy not been issued would be, entitled to indemnity from the United States of America or any agency thereof, under any agreement entered into by the United States of America, or any agency thereof, with any person or organization.
2. to any liability resulting from the hazardous properties of nuclear material, if:
  - a. the nuclear material is at any nuclear facility owned by or operated by or on behalf of an insured, or has been discharged or dispersed therefrom;
  - b. the nuclear material is contained in spent fuel or waste at any time possessed, handled, used, processed, stored, transported or disposed of by or on behalf of an insured; or
3. to any liability arising out of the furnishing, by an insured, of services, materials, parts or equipment in connection with the planning, construction, maintenance, operation or use of any nuclear facility, but if such facility is located within the United States of America, its territories or possessions or Canada, this exclusion applies only to injury to or destruction of property at such nuclear facility.

As used in this endorsement:

1. "hazardous properties" includes radioactive, toxic or explosive properties;
2. "nuclear material" means "source material," "special nuclear material" or "by-product material;"
3. "source material," "special nuclear material" and "by-product material" have the meanings given them in the Atomic Energy Act of 1954 or in any law amendatory thereof;

4. "spent fuel" means any fuel element or fuel component, solid or liquid, which has been used or exposed to radiation in a nuclear reactor;
5. "waste" means any waste material:
  - a. containing by-product material; and
  - b. resulting from the operation by any person or organization of any nuclear facility included within the definition of nuclear facility under paragraph 6. below;
6. "nuclear facility" means:
  - a. any nuclear reactor;
  - b. any equipment or device designed or used for:
    - i. separating the isotopes of uranium or plutonium;
    - ii. processing or utilizing spent fuel; or
    - iii. handling, processing or packaging waste;
  - c. any equipment or device used for the processing, fabricating or alloying of "nuclear material" if at any time the total amount of such material in the custody of the insured at the premises where such equipment or device is located consists of or contains more than 25 grams of plutonium or uranium 233 or any combination thereof, or more than 250 grams of uranium 235;
  - d. any structure, basin, excavation, premises or place prepared or used for the storage or disposal of waste and includes the site on which any of the foregoing is located, all operations conducted on such site and all premises used for such operations;
7. "nuclear reactor" means any apparatus designed or used to sustain nuclear fission in a self-supporting chain reaction or to contain a critical mass of fissionable material;

With respect to injury to or destruction of property, the word "injury" or "destruction" includes all forms of radioactive contamination of property.

All other terms of the policy remain unchanged.

**COMMERCIAL UMBRELLA LIABILITY**

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**PROFESSIONAL SERVICES EXCLUSION**

This endorsement modifies insurance provided under the following:

**COMMERCIAL UMBRELLA LIABILITY COVERAGE PART**

A. Exclusion 7. is deleted from SECTION I - COVERAGES, 2. Exclusions, A.

B. The following is added to SECTION I - COVERAGES, 2. Exclusions, B.:

Under Coverage A - Excess Liability and Coverage B - Umbrella Liability, this insurance does not apply to any liability arising out of the rendering or failure to render any "professional services;"

All other terms of the policy remain unchanged.

**COMMERCIAL UMBRELLA LIABILITY**

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**EXCLUSION – PRODUCTS-COMPLETED  
OPERATIONS HAZARD**

This endorsement modifies insurance provided under the following:

**COMMERCIAL UMBRELLA LIABILITY COVERAGE PART**

- A. The following is added to SECTION I -COVERAGES, 2. Exclusions, B.
- B. Under Coverage A - Excess Liability and Coverage B - Umbrella Liability:

This insurance does not apply to:

- 1. bodily injury or property damage included within the "products-completed operations hazard;"

## COMMERCIAL EXCESS/UMBRELLA LIABILITY

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

**AMENDMENT - SCHEDULE OF UNDERLYING**

This endorsement modifies insurance provided under the following:

COMMERCIAL EXCESS LIABILITY COVERAGE PART  
COMMERCIAL UMBRELLA LIABILITY COVERAGE PART

Item 4. of the Declarations is amended as follows:

The following is ☒ Added ☐ Amended ☐ Deleted

## 4. Underlying Insurance:

| Coverage/Carrier/Policy Number                                       | Policy Term   | Limits  |
|--|---|---|
| Auto Liability<br>Federal Insurance Co<br>73588735                   | 11/30/2017 to 11/30/2018  | \$1,000,000 Combined Single Limit   |
| General Liability<br>Navigators Insurance Company<br>CH17NCP02048000 | <input checked="" type="radio"/> Occurrence <input type="radio"/> Claims Made<br>11/30/2017 to 11/30/2018<br><br><input type="checkbox"/> Per Project <input type="checkbox"/> Per Location | \$1,000,000 Each Occurrence<br>\$1,000,000 Personal and<br>Advertising<br>Injury-any one person or<br>organization<br><br>\$2,000,000 General Aggregate<br>Not Covered - Product/CompOps<br>Aggregate |
| Employers Liability<br>Federal Insurance Co<br>71751699              | 11/30/2017 to 11/30/2018  | \$1,000,000 BI by Accident - Each<br>Accident<br>\$1,000,000 BI by Disease - Each<br>Employee<br>\$1,000,000 BI by Disease - Policy<br>Limit  |

Employee Benefits Liability  
Navigators Insurance Company  
CH17NCP02048000

☐ Occurrence ☒ Claims Made  
Retroactive Date: 10/1/2014  
11/30/2017 to 11/30/2018

\$1,000,000 Each Employee  
\$1,000,000 Aggregate

Foreign Liability  
Navigators Insurance Company  
PH17FPK0BIG0RNV

☒ Occurrence ☐ Claims Made  
11/30/2017 to 11/30/2018

\$1,000,000 Each Occurrence  
\$2,000,000 Aggregate

All other terms of the policy remain unchanged.

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

## **CAP ON LOSSES FROM CERTIFIED ACTS OF TERRORISM**

This endorsement modifies insurance provided under the following:

COMMERCIAL UMBRELLA LIABILITY COVERAGE PART  
COMMERCIAL EXCESS LIABILITY COVERAGE PART  
COMMERCIAL FOLLOW FORM EXCESS LIABILITY POLICY

If aggregate insured losses attributable to "certified acts of terrorism" exceed \$100 billion in a calendar year and we have met our insurer deductible under the Terrorism Risk Insurance Act, we shall not be liable for the payment of any portion of the amount of such losses that exceeds \$100 billion, and in such case insured losses up to that amount are subject to pro rata allocation in accordance with procedures established by the Secretary of the Treasury.

"Certified act of terrorism" means an act that is certified under the federal Terrorism Risk Insurance Act by the Secretary of the Treasury, in accordance with the provisions of the federal Terrorism Risk Insurance Act, to be an act of terrorism pursuant to such Act. The criteria contained in the Terrorism Risk Insurance Act for a "certified act of terrorism" include the following:

1. The act resulted in insured losses in excess of \$5 million in the aggregate, attributable to all types of insurance subject to the Terrorism Risk Insurance Act; and
2. The act is a violent act or an act that is dangerous to human life, property or infrastructure and is committed by an individual or individuals as part of an effort to coerce the civilian population of the United States or to influence the policy or affect the conduct of the United States Government by coercion.

Any other terms of the policy that conflict with this endorsement are deleted.

COMMERCIAL UMBRELLA LIABILITY  
NAV-UMB-100 (1/05)

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

## **Amendment of Declarations - Named Insured**

This endorsement modifies insurance provided under the following:

### **COMMERCIAL UMBRELLA COVERAGE PART**

Item 1. of the Declarations is amended to include:

Cypress Pharmaceuticals, Inc.  
Gaine, Inc.  
GTA GP, Inc.  
GTA LP, Inc.  
Hawthorn Pharmaceuticals, Inc.  
Macoven Pharmaceuticals, LLC  
Pernix Manufacturing, LLC  
Pernix Manufacturing, LLC dba Great Southern Laboratories  
Pernix Therapeutics, LLC  
Respicopea, Inc.  
Respicopea, Limited  
Pernix Sleep Inc. dba Somaxon Pharmaceuticals, Inc  
Zinterests, LLC  
Pernix Ireland Ltd f/k/a Worrigan Limited  
Pernix Ireland Pain, Limited f/k/a Ferrimill Ltd

All other terms of the policy remain unchanged.